MEDICARE HOSPITAL INPATIENT OPERATING AND CAPITAL PAYMENT FISCAL YEAR 2013 PROPOSED RULE

SUMMARY

On April 24, 2012, the Centers for Medicare and Medicaid Services (CMS) released its proposed rule for federal fiscal year (FY) 2013 changes to Medicare's acute care hospital inpatient prospective payment system (IPPS) and long-term care hospital (LTCH) prospective payment system. The payment rates and policies described in the proposed rule would affect Medicare's operating and capital payments for short-term acute care hospital inpatient services and services provided in long-term care hospitals paid under their respective prospective payment systems as well as payments for inpatient services provided by certain "IPPS-Exempt" providers, such as cancer and children's hospitals, and religious nonmedical health care institutions. The proposed rule is scheduled for publication in the *Federal Register* on May 11, 2012 with a 60-day comment period (from the date of public display) closing on June 25, 2011. The proposed rates and most of the proposed policy changes, as modified by the final rule due to be published by August 1, 2012, will be effective October 1, 2012.

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I. PPS Rate Updates and Impact of the Proposed Rule

CMS estimates that the proposed rule would increase Medicare's operating payments to the approximately 3,400 acute care hospitals paid under the IPPS by approximately $904 million in FY 2013, or 0.9 percent, taking into account a rate increase of 2.3 percent for hospitals which successfully report quality measures and all other proposed policies affecting payment. After taking into account the expiration of certain statutory provisions which had provided special temporary increases in payments to hospitals and other proposed changes, CMS projects that total Medicare spending on inpatient hospital services will increase by about $175 million in FY 2013.

IPPS capital payments are projected to decrease slightly in FY 2013 compared to FY 2012, with average payments per case shown to be about 0.2 percent lower despite a capital payment rate increase of about 0.7 percent. A major factor is that outlier payments in FY 2013 are expected to be lower than in FY 2012. Based on current estimates, actual outlier payments in FY 2012 will exceed the level projected when the operating and capital outlier offsets were set for FY 2012. The proposed rule would update the capital payment rate by about 0.7 percent, which is the net result of an inflation update factor of 1.3 percentage points, a reduction of 0.8 percentage points for documentation and coding changes in FY 2010 (discussed in section II.B below), and an increase of 0.2 percentage points due to a lower outlier adjustment factor in FY 2013 compared to FY 2012.

CMS projects that LTCH payments for about 440 LTCHs will increase by approximately $100 million in FY 2013, or 1.9 percent, under the proposed rule. CMS proposes an annual update to LTCH payment rates of 2.1 percent. As explained in section VII below, in addition to the inflation update (adjusted as required by statute), the 2.1 percent update to LTCH payment rates would be reduced by approximately 1.3 percent to a net 0.8 percent due to a proposed "one-time" budget neutrality adjustment applied to discharges on or after December 29, 2012.

Inpatient Hospital Operating Update for FY 2012

Under the proposed rule, the inpatient hospital update to the payment rates would be 2.3 percent for hospitals that successfully participate in the Hospital Inpatient Quality Reporting (IQR) Program. Hospitals that do not successfully participate in the IQR Program would receive a 2.0 percentage point reduction or a payment rate update of 0.3 percent. The IPPS rate update applies to the national and Puerto Rico operating standardized amounts and to the hospital-specific rates used in payment for sole community hospitals and Medicare-dependent hospitals.

The 2.3 percent rate increase is the net result of a market basket increase projected to be 3.0 percentage points, less an annual multi-factor productivity (MFP) adjustment projected to be -0.8 percentage points and a statutory update reduction of 0.1 percentage points. Both the annual productivity adjustment and the 0.1 percentage point reduction are required by the Affordable Care Act (ACA). Finally, the standardized amounts would be increased 0.2 percentage points reflecting the net documentation and coding adjustment discussed in section

II.B below. The Bureau of Labor Statistics publishes the official measure of private nonfarm business MFP; historical data on this series are available at http://www.bls.gov/mfp. Projections of MFP for IPPS payment updates are developed by IHS Global Insight, Inc. an economic forecasting firm which also prepares the market basket forecasts, using a methodology described in the proposed rule. More technical information on the MFP is available from BLS: http://www.bls.gov/mfp/mprtech.pdf. The final rule will reflect more recent projections of the market basket and productivity adjustments.

The proposed update to the national standardized amounts is summarized in the table below:

FY 2013 inflation (market basket) update	3.0%
Multifactor productivity adjustment	-0.8%
Additional -0.1 percentage point update adjustment required by the ACA	-0.1%
Subtotal – payment rate inflation update	*2.1%*
Net adjustment for documentation and coding	+0.2%
Net increase in payment rates	2.3%

As discussed in discussed in section II.B below, the proposed net documentation and coding adjustment applicable to the update of hospital-specific rates of sole community hospitals (SCHs) is -1.3 percentage points rather than the +0.2 net percentage points adjustment applicable to the standardized amounts. Therefore, the update factor proposed for hospital-specific rates is 0.8 percent (which equals the 2.1 percent subtotal in the table above minus 1.3 percentage points for documentation and coding).

Additional Factors Affecting Payment Impact Analysis

While the proposed FY 2013 standardized amounts increase 2.3 percent compared to FY 2012, the payment impact analysis shows aggregate payments increasing 0.9 percent. The additional factors affecting the aggregate payment impact estimates are summarized in the table below:

Contributing Factor	**Aggregate National Impact**
Lower SCH hospital-specific rate update (0.8% compared to 2.3% for the national standardized amounts)	-0.1%
Implementation of readmissions reduction provision (described in section IV.A. below)	-0.3%
Lower projected outlier payments in FY 2013	-0.9%
Expiration of Medicare-dependent hospital (MDH) provision	-0.1%
Implementation of frontier hospital wage index floor	+0.1%
Expiration of section 508 reclassification provision	-0.1%
Total	-1.4%

CMS currently projects that actual outlier payments in FY 2012 will be about 6.0 percent compared to the 5.1 percent outlier offset. For FY 2013, CMS again will apply a 5.1 percent outlier offset and it projects that payments will equal the 5.1 percent offset. Thus, compared to FY 2012, outlier payments in FY 2013 are projected to be 0.9 percent lower.

The CMS impact analysis shows significant variation in the net payment change of the proposed rule among hospitals, with an average projected increase of 1.2 percent for hospitals in large urban areas compared to a projected decrease of 0.5 percent for hospitals in rural areas. Rural hospitals' aggregate payments increase 2.1 percent for geographic reclassification but they fall 0.9 percent for expiration of the MDH provision, 0.3 percent for the readmissions reduction program, 0.3 percent for wage index changes, 0.3 percent for budget neutrality of wage index rural floor, and 0.1 percent due to DRG reclassification/ recalibration. The rural hospital impact also reflects the lower rate update applicable to the hospital-specific rate of SCHs. Regional changes in operating payments range from an increase of 2.4 percent for urban hospitals in the Pacific region to a decrease of 2.1 percent for rural New England hospitals. The regional variation results primarily from differences in the effects of the wage index rural floor and from geographic classifications, which are budget neutral in the aggregate, but also from geographic variation in the impact of expiring provisions such as additional payments for MDHs and section 508 wage reclassifications.

Detailed impact estimates are displayed in Table I of the proposed rule (reproduced in Appendix B of this summary). The following table shows the impact by major hospital category.

Hospital Type	All Proposed Rule Changes
All Hospitals	0.9%
Large Urban	1.2%
Other Urban	0.9%
Rural	-0.5%
Major Teaching	0.8%

Proposed IPPS Standardized Amounts

The proposed rule projects the following rates effective October 1, 2012, which reflect all adjustments to the standardized amounts including the adjustment for documentation and coding. For hospitals that fail to submit quality inpatient reporting data, the 2.3 percent update will be reduced by 2.0 percentage points to total 0.3 percent.

TABLE 1A.—PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (68.8 PERCENT LABOR SHARE/31.2 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1)

Full Update (2.1 Percent)		Reduced Update (0.1 Percent)	
Labor-related	**Nonlabor-related**	**Labor-related**	**Nonlabor-related**
$3,664.03	$1,661.59	$3,592.26	$1,629.04

TABLE 1B.—PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX IS LESS THAN OR EQUAL TO 1)

Full Update (2.1 Percent)		Reduced Update (0.1 Percent)	
Labor-related	**Nonlabor-related**	**Labor-related**	**Nonlabor-related**
$3,301.88	$2,023.74	$3,237.21	$1,984.09

TABLE 1C.—PROPOSED ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR PUERTO RICO, LABOR/NONLABOR

	Rates if Wage Index is Greater Than 1		Rates if Wage Index is Less Than or Equal to 1	
	Labor	**Nonlabor**	**Labor**	**Nonlabor**
National	$3,664.03	$1,661.59	$3,301.88	$2,023.74
Puerto Rico	$1,583.10	$966.17	$1,580.55	$968.72

TABLE 1D.—PROPOSED CAPITAL STANDARD FEDERAL PAYMENT RATE

	Rate
National	$424.42
Puerto Rico	$206.82

Outlier Payments and Threshold

Hospitals receive additional IPPS payments for "outlier" cases involving extraordinarily high costs. To qualify for outlier payments, a case must have costs greater than the sum of the prospective payment rate for the DRG, any IME and DSH payments, any new technology add-on payments, and the "outlier threshold" or "fixed-loss" amount (a dollar amount by which the costs of a case must exceed payments in order to qualify for an outlier payment). The sum of these components is referred to as the outlier "fixed-loss cost threshold." To determine whether the costs of a case exceed the fixed-loss cost threshold, a hospital's CCR is applied to the total covered charges for the case to convert the charges to estimated costs. Payments for

eligible cases are then made based on a marginal cost factor, which is 80 percent of the estimated costs above the fixed-loss cost threshold.

For FY 2013, CMS continues to set the target for total outlier payments at 5.1 percent of total operating DRG payments (including outlier payments). The proposed rule applies the same methodology used since FY 2009 (73 FR 48763 through 48766) to calculate a fixed-loss cost threshold consistent with the 5.1 percent target. CMS proposes an outlier fixed-loss cost threshold for FY 2013 equal to the prospective payment rate for the DRG, plus any IME and DSH payments, and any add-on payments for new technology, plus $27,425, which represents a $5,040 (or 22.5 percent) increase from the final FY 2012 final outlier fixed-loss cost threshold of $22,385.

Since FY 2009, the outlier fixed-loss cost threshold has been between $20,185 and $23,140. A significant contributing factor to the large increase for FY 2013 is the 2-year charge inflation factor of 14.06 percent which was applied to the FY 2011 MedPAR claims used to compute the FY 2013 outlier fixed-loss cost threshold; the 2-year charge inflation factor applied to the FY 2010 MedPAR claims used to compute the FY 2012 final outlier fixed-loss cost threshold was 7.94 percent. CMS is concerned about the large increases in both the charge inflation factor and the outlier fixed-loss cost threshold and invites public comments. It also notes that swings in the actual outlier payout – from 4.7 percent of actual total DRG payments in FY 2011 to 6.0 percent of actual total DRG payments in FY 2012 – suggest a potential for improving the estimation methodology to meet the 5.1 percent target. CMS welcomes public comment on ways to enhance the accuracy of the methodology.

The proposed rule does not include the hospital VBP payment adjustment and the readmissions payment adjustment in the outlier threshold calculation or the outlier offset to the standardized amount consistent with the proposed definition of the base operating DRG payment amount for these programs. Outlier payments would continue to be calculated based on the unadjusted base DRG payment amount (as opposed to using the operating base DRG payment amount adjusted by the hospital readmissions payment adjustment and the hospital VBP adjustment). Note, however, that CMS includes both of these adjustments in total operating DRG payments for the purpose of determining budget neutrality of the IPPS.

II. Proposed Changes to DRG Classifications and Relative Weights

A. MS-DRGs for FY 2013

In the proposed rule for FY 2013, CMS continues to use the Medicare severity diagnosis-related group (MS-DRG) classification system. Proposed changes in specific MS-DRGs are described in section II.E. below. For a detailed description of the process used to develop the MS-DRGs, CMS refers readers to the FY 2010 final rule (published in the *Federal Register* at 74 FR 43764 through 43766), the FY 2011 final rule (75 FR 50053 through 50055), and the FY 2012 final rule (76 FR 51485 through 51487).

B. FY 2013 Documentation and Coding Adjustment

The FY 2013 proposed rule continues the process of documentation and coding adjustments begun in FY 2007 when the transition to MS-DRGs began. Under this process, CMS makes adjustments in the standardized amounts to the extent it estimates that increases in the average case-mix index (CMI) are due to improved medical record documentation and more complete and accurate coding rather than reflecting real increases in the severity of cases that require additional hospital resources.

A discussion of statutory requirements and CMS rulemaking through FY 2011 regarding payment adjustments to remove the effects of documentation and coding increases on payments appears in Appendix A of this summary. That history includes both prospective and retrospective adjustments relating to documentation and coding changes occurring during FYs 2008 and 2009. That is, adjustments have been made to eliminate the effects of these documentation and coding changes on future payments, and separately to recoup payments made in those years as a result of documentation and coding improvements.

FY 2012 final rule adjustments to the standardized amounts. In the FY 2012 proposed rule, CMS applied a prospective adjustment of -3.15 percent to FY 2012 payment rates in addition to applying an adjustment of -2.9 percent to recoup the remaining FY 2008 and FY 2009 overpayments as required by law. (The 2.9 percentage point reduction had no net effect on the standardized amounts because it replaced the 2.9 percentage point reduction which had been applied in FY 2011 for recoupment.) In the FY 2012 final rule, CMS addressed concerns expressed by many commenters about the fiscal impact that large payment reductions would have on hospitals. In response, CMS finalized a prospective adjustment of -2.0 percent, a reduction of 1.15 percentage points compared to the proposed rule level -3.15 percent. Applying a prospective adjustment of -2.0 percent in FY 2012 left a remaining prospective of adjustment of -1.9 percent to be applied in the future. The table below summarizes the adjustments for FY 2012 for documentation and coding for IPPS hospitals.

Final Rule, FY 2012 MS-DRG Documentation and Coding Adjustment (Operating Standardized Amounts)

Required Prospective Adjustment for FYs 2008-2009	Remaining Required Recoupment Adjustment for FYs 2008-2009	Total Remaining Adjustment	Prospective Adjustment for FY 2012	Recoupment Adjustment to FY 2012 Payments	Remaining Prospective Adjustment
-3.90%	-2.90%	-6.80%	-2.00%	-2.90%	-1.90%

FY 2013 proposed rule adjustments to the standardized amounts. For FY 2013, CMS proposes to complete the prospective portion of the statutorily required adjustment by applying a

-1.9 percent adjustment to the standardized amount for FY 2013. This adjustment would remove the remaining effect of the documentation and coding changes that do not reflect real changes in case-mix that occurred in FY 2008 and FY 2009, as estimated by CMS.

Following a similar analysis to the analyses applied in previous years' rulemaking to examine CMI changes in FY 2008 and FY 2009, CMS analyzed CMI changes in FY 2010 for the FY 2013 proposed rule. The analysis showed an estimated increase in documentation and coding-related CMI of 0.8 percentage points in FY 2010. To eliminate the effect of coding or classification changes that do not reflect real changes in case-mix, the proposed rule applies a prospective adjustment of -0.8 percent to the standardized amounts. As shown in the table below, the proposed FY 2013 adjustment equals -1.90 percentage points plus -0.80 percentage points for a total adjustment of -2.70 percentage points. The proposed rule also removes the FY 2012 onetime recoupment adjustment of 2.90 percentage points resulting in a net documentation and coding adjustment for FY 2013 of 0.2 percentage points.

Proposed Rule, FY 2013 MS-DRG Documentation and Coding Adjustment (Operating Standardized Amounts)

	Remaining Prospective Adjustment for 2008-2009	**Prospective Adjustment for FY 2010**	**Proposed Prospective Adjustment for FY 2013**	**Removal of Onetime Recoupment Adjustment in FY 2013**	**Combined Proposed Documentation & Coding Adjustment for FY 2013**
Level of Adjustments	-1.90%	-0.80%	-2.70%	2.90%	0.20%

With respect to hospital-specific rates, in the FY 2012 final rule CMS applied a prospective documentation and coding adjustment of -2.0 percent leaving an additional -0.5 percent adjustment to the hospital-specific payment rates to complete prospective adjustments required to remove CMS' estimate of the documentation and coding-related changes in FY 2008 and FY 2009. In past rulemaking, CMS had determined that a -5.4 percent adjustment was required to eliminate the full effect of documentation and coding changes on future payments to SCHs and MDHs. For FY 2011, an adjustment of -2.9 percent was made. For FY 2013, CMS proposes to apply the -0.5 percent adjustment necessary to complete removal of the FY 2008 and FY 2009 CMI effects as well as to apply an additional adjustment of -0.8 percentage points to remove the FY 2010 documentation and coding-related effect discussed above.

For FY 2013, CMS determined, as it had for FY 2012, that no further adjustment is needed to correct the Puerto-Rico specific rate for FY 2013 for CMI changes in FY 2008, FY 2009 and FY 2010. CMS made an adjustment of -2.6 percent for FY 2011, which CMS estimates is the entire adjustment required to eliminate the effects of documentation and coding changes on future payment under the Puerto Rico rate.

C. Refinement of the MS-DRG Relative Weight Calculation

Beginning in FY 2009, the relative weights were fully cost-based, having completed the 3-year transition begun in the FY 2007 final rule from weights based on hospitals' billed charges to weights based on hospitals' costs. Costs are determined by calculating cost-to-charge ratios (CCRs) for 15 cost centers from hospital cost reports and using national CCRs to convert billed charges to costs. The final IPPS rules for FY 2007 (71 FR 47882) and FY 2008 (72 FR 47199) describe the details of the cost-based weight calculation methodology and this proposed rule includes a summary of the methodology with a table showing the lines on the cost report and the corresponding revenue codes used to create the 15 national cost center CCRs (pp. 203-226 of display copy).

The FY 2013 proposed rule again addresses the issue of charge compression affecting billed charges for high cost services and the cost report changes made in recent years to get more refined cost data for Implantable Devices Charged to Patients, CT, MRI, and Cardiac Catheterization. As stated in previous years' rulemaking, CMS had anticipated being able to consider FY 2010 cost report data for Implantable Devices Charged to Patients in calculating relative weights for FY 2013. In this proposed rule, CMS reports, however, that technical difficulties with the cost report data (noted in section II.F. below) preclude use of the new cost center data even though FY 2010 HCRIS includes these data for a sizeable number of hospitals. CMS reports a compounding problem; the corresponding information regarding charges for implantable devices on hospital claims is not yet available in the MedPAR file. Missing a breakout in the MedPAR file of charges associated with implantable devices to correspond to the costs of implantable devices on the cost report, CMS proposes to continue computing the relative weights with the current CCR that combines the costs and charges for supplies and implantable devices.

Looking forward, the proposed rule states: *"When we do have the necessary supplies and implantable device data on the claims in the MedPAR file to create distinct CCRs for supplies and implantable devices, perhaps for FY 2014, we also hope that we will have data for an analysis of creating distinct CCRs for MRI, CT scans, and cardiac catheterization. Prior to proposing to create these CCRs, we will first thoroughly analyze and determine the impacts of the data. Distinct CCRs for implantable devices, MRIs, and CT scans would be used in the calculation of the relative weights only if they were first finalized through rulemaking."*

D. Preventable Hospital Acquired Conditions (HACs) Including Infections

Since October 1, 2008, an inpatient hospital discharge is not assigned to a higher paying MS-DRG if a selected hospital-acquired condition (HAC) was not present on admission (POA). Thus, the case will be paid as though the secondary diagnosis was not present. The selected HACs that CMS determines, in consultation with the CDC, are required to have at least two conditions that: (1) are high cost, high volume or both, (2) would result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and (3) could reasonably have been prevented through the application of evidence-based guidelines. Under CMS' policy, Medicare does not pay at the higher complication or comorbidity (CC) or major complication or comorbidity (MCC) amount when a selected HAC

diagnosis code is reported with a POA indicator of "N" (condition not present on admission) or "U" (documentation is insufficient to determine if condition was present on admission). HACs coded with a POA indicator of "Y" (condition was present on admission) or "W" (hospital has determined that based on data and clinical judgment it is not possible to document when the onset of the condition occurred) are considered POA and the condition can cause an increase in payment at the CC/MCC level.

Beginning on or after January 1, 2011, hospitals using the new 5010 format (Version 5010 of the electronic transaction standards) no longer need to report a POA indicator of "1" for codes exempt from POA reporting (the field should be left blank). For claims that continue to be submitted using the 4010 electronic transmittal standards format, the POA indicator of "1" is still required.

CMS has translated the current ICD-9-CM HAC list into codes using the ICD-10-CM and ICD-10-PCS classification system. The translation list is available on the CMS Web site: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/icd10_hacs.html. CMS encourages comments on these translations through the HACs Web page using the CMS ICD-10-CM/PCS HAC Translation Feedback Mailbox under the Related Links section titled "CMS HAC Feedback". CMS will subject the final HAC translation list to formal rulemaking.

CMS awarded a contract in 2009 to Research Triangle Institute, International (RTI) to evaluate the impact of the HAC-POA policies. The FY 2011 IPPS/LTCH PPS summarized findings to data based on FY 2009 and FY 2010 MedPAR data (http://www.cms.gov/HospitalAcqCond/01_Overview.asp). Additional information about the RTI evaluation can be found on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/index.html.

Proposed Changes to the HAC Policy for FY 2013

a. *Proposed Additional Diagnosis Codes to Existing HACs*. CMS is proposing to add two diagnosis codes, 999.32 (Bloodstream infection due to central venous catheter) and 999.33 (Local infection due to central venous catheter) to the Vascular Catheter-Associated Infection HAC Category for FY 2013. These codes were effective October 1, 2011 and were created in response to a request to better identify specific types of infections that occur as a result of central venous catheter placement. Both of these diagnosis codes have a CC designation. CMS invites public comments on this proposal.

b. *Proposal to Add New HAC: Surgical Site Infection (SSI) Following Cardiac Implantable Electronic Device (CIED) Procedures*. For FY 2013, CMS proposes to add SSI following CIED Procedures as a HAC and invites public comment on this proposal.

CMS proposes to identify the condition with a subset of discharges with ICD-9-CM diagnosis code 996.61 (Infection and inflammatory reaction due to cardiac device, implant and graft) or 998.59 (Other postoperative infection) that also have one or more of a specified list of 21 ICD-9-CM procedure codes associated with CIED procedures (see table below).

CMS states that SSI Following CIED Procedures meets the three criteria for inclusion on the HAC list. First, the condition is one that is high cost and high volume. Based on the Medicare claims data in the FY 2011 MedPAR file there were 859 inpatient discharges coded with this condition as specified by diagnosis code 996.61 or 998.59 when reported with one or more of the associated procedure codes; the cases had an average cost of $51,795 for the entire hospital stay. Of these 859 inpatient discharges, 583 claims indicated the condition was POA with an average cost of $41,999 and 276 claims indicated the condition was not POA with an average cost of $72,485. CMS also states that several large published studies support their conclusions that this condition is high cost. Second, the condition is a CC under the MS-DRG system and CMS has not identified any additional administrative or operational difficulties associated with this condition. Third, there are widely recognized guidelines for the prevention of SSI Following CIED Procedures and a large randomized controlled trial demonstrated that prophylactic preoperative antibiotics reduced CIED by 81 percent in patients. CMS is particularly interested in comments on the degree to which SSI Following CIED Procedures is reasonably preventable through the application of evidence-based guidelines.

c. *Proposal to Add New HAC: Iatrogenic Pneumothorax with Venous Catherization.* For FY 2013, CMS proposes to add Iatrogenic Pneumothorax with Venous Catherization as a HAC and invites public comment on this proposal.

CMS had proposed Iatrogenic Pneumothorax more generally as a HAC in the FY 2009 IPPS rulemaking but did not finalize this proposal because commenters' raised concerns about the preventability of the condition when following evidence-based guidelines.
Commenters also offered suggestions to exclude certain procedures or situations, such as central line placement and the use of a ventilator, if this condition was selected as a HAC. To address these concerns, CMS has reviewed changes in the standard of care and evidence-based guidelines to identify specific situations where Iatrogenic Pneumothorax would be considered reasonably preventable and identified venous catherization as a situation where this condition is preventable.

CMS proposes to identify the condition with a subset of discharges with ICD-9-CM diagnosis code 512.1 (Iatrogenic pneumothorax) in combination with the associated procedure code 38.93 (Venous catherization, NEC). CMS believes that by limiting the proposal to include only venous catherization, they have improved their ability to accurately identify discharges with this condition. Although they are not proposing any exclusion criteria, they welcome public comment on this issue.

CMS states that Iatrogenic Pneumothorax with Venous Catherization meets the three criteria for inclusion on the HAC list. First, the condition is one that is high cost and high volume. Based on the Medicare claims data in the FY 2011 MedPAR file there were 4,467 inpatient discharges coded for this condition as specified by diagnosis code 512.1 reported with procedure code 38.93; these cases had an average cost of $39,128 for the entire hospital stay. Of these 4,467 inpatient discharges, 612 claims indicated the condition was POA with an average cost of $26,693 and 3,855 claims indicated the condition was NPOA with an average cost of $41,102. Second, the condition is a CC under the MS-DRG system. Third, there are

widely recognized guidelines for the prevention of this condition and CMS believes that Iatrogenic Pneumothorax in the context of venous catherization is reasonably preventable through application of these evidence-based guidelines. CMS cites the recommended use of ultrasound for the placement of all central venous catheters in the AHRQ 2001 report "Making Health Care Safer: A Critical Analysis of Patient Safety Practices" (AHRQ Publication No. 01-E058) and the 2012 guidelines for performing ultrasound guided vascular cannulation published by the American Society of Echocardiography and the Society of Cardiovascular Anesthesiologists (Anesthesia and Analgesia, 114(1):46-72). CMS is particularly interested in comments on how limiting the condition to situations in which it occurs with venous catherization influences preventability, and if additional limits should be considered in the context of venous catherization.

The table below reflects the current HAC categories, with the additions and changes summarized above identified in italics.

HAC	CC/MCC (ICD-9-CM Code)
Foreign Object Retained After Surgery	998.4 (CC) 998.7 (CC)
Air Embolism	999.1 (MCC)
Blood Incompatibility	999.60 (CC) 999.61 (CC) 999.62 (CC) 999.63 (CC) 999.69 (CC)
Pressure Ulcer Stages III & IV	707.23 (MCC) 707.24 (MCC)
Falls and Trauma: - Fracture - Dislocation - Intracranial Injury - Crushing Injury - Burn - Other Injuries	Codes within these ranges on the CC/MCC list: 800-829 830-839 850-854 925-929 940-949 991-994
Catheter-Associated Urinary Tract Infection (U	996.64 (CC) Also excludes the following from acting as a CC/MCC: 112.2 (CC) 590.10 (CC) 590.11 (MCC) 590.2 (MCC) 590.3 (CC) 590.80 (CC) 590.81 (CC) 595.0 (CC)

HAC	CC/MCC (ICD-9-CM Code)
	597.0 (CC) 599.0 (CC)
Vascular Catheter Associated Infection	999.31 (CC)
Manifestations of Poor Glycemic Control - Diabetic Ketoacidosis - Nonketotic Hyperosmolar Coma - Hypoglycemic Coma - Secondary Diabetes with Ketoacidosis - Secondary Diabetes with Hyperosmolarity	250.10-250.13 (MCC) 250.20-250.23 (MCC) 251.0 249.10-249.11 (MCC) 249.20-249.21 (MCC
Surgical Site Infection, Mediastinitis, Followin Coronary Artery Bypass Graft (CABG)	519.2 (MCC) And one of the following procedure codes: 36.10–36.19
Surgical Site Infection Following Certain Orthopedic Procedures - Spine - Neck - Shoulder - Elbow	996.67 (CC) 998.59 (CC) And one of the following procedure codes: 81.01-81.08, 81.23-81.24, 81.31-81.38, 81.83, 81.85
Surgical Site Infection Following Bariatric Sur for Obesity - Laparoscopic Gastric Bypass - Gastroenterostomy - Laparoscopic Gastric Restrictive Surgery	Principal Diagnosis – 278.01 539.01 (CC) 539.81 (CC) 998.59 (CC) And one of the following procedure codes: 44.38, 44.39, or 44.95
Deep Vein Thrombosis and Pulmonary Emboli Following Certain Orthopedic Procedures - Total Knee Replacement - Hip Replacement	415.11 (MCC) 415.13 (MCC) 415.19 (MCC) 453.40-453.42 (MCC) And one of the following procedure codes: 00.85-00.87, 81.51-81.52, or 81.54
Surgical Site Infection (SSI) Following Cardia Implantable Electronic Device (CIED) Proced	*996.61(CC) 998.59(CC) And one of the following procedure codes: 00.50-00.54, 37.80-37.83, 37 37.87, 37.94, 37.96, 37.98, 3 37.77, 37.79, or 37.89*
Iatrogenic Pneumothorax with Venous Catheri	*512.1(CC) with procedure c 38.93*

CMS estimates the Medicare savings from the HAC payment provision for the next 5 fiscal years as follows:

Year	Savings In Millions
FY 2013	$24
FY 2014	$26
FY 2015	$28
FY 2016	$30
FY 2017	$33

E. Changes to Specific DRG Classifications

In this proposed rule, CMS invites public comment on proposed MS-DRG classification changes as well as proposals to maintain certain existing MS-DRG classifications based on analyses of claims data. CMS also encourages input from stakeholders concerning the annual IPPS updates when that input is made by December of the year prior to the next annual proposed rule update. To be considered for any update or change in FY 2013, comments and suggestions should have been submitted by early December 2011.

1. Pre-Major Diagnostic Categories (Pre-MDCs)

a. Ventricular Assist Devices (VADs): CMS received a request to restructure MS-DRGs 001 (Heart Transplant or Implant of Heart Assist System with MCC) and 002 (Heart Transplant or Implant of Heart Assist System without MCC) by removing all of the procedure codes that describe the insertion of a VAD, leaving only procedure codes 33.6 (Combined heart-lung transplantation) and 37.51 (Heart transplantation) in the heart transplant DRGs and to create new MS-DRGs for the remaining device codes. The requestor stated that within the existing MS-DRG groupings, CMS is underpaying for services to patients who have a VAD implanted and overpaying for services to patients who have heart transplants. CMS is not proposing to make any changes to the structure of MS-DRG's 001 and 002 and invites public comment.

CMS reviewed the FY 2011 MedPAR file and found that the average length of stay for heart transplantations and VAD implantation cases are very similar and that the average cost for VAD implantation cases alone is higher that the average cost of heart transplantation cases. CMS believes that the higher average cost for VAD implantation is due to the cost of the device. CMS reiterates that the IPPS is not designed to pay solely for the cost of devices and that the MS-DRG system is a patient classification system that provides an average means of relating the type of patients to the costs incurred by the hospital. Further, to create new MS-DRGs specific to VAD implantation would require basing the MS-DRG almost exclusively on one procedure code, 37.66 (Insertion of implantable heart assist system (VAD)), representing a single procedure and currently one manufacturer with FDA approval. CMS is concerned that increasing payment for one device would set an "unwarranted precedent".

b. Allogenic Bone Marrow Transplant: During the comment period for the FY 2012 IPPS proposed rule, which included proposals related to bone marrow transplants, CMS received a comment recommending that MS-DRG 014 be subdivided into two MS-DRGs based on related and unrelated transplant donor source. CMS is not proposing to subdivide MS-DRG 014 based on donor source and invites public comment.

CMS' analysis of the FY 2011 MedPAR file found that MS-DRG could be divided into 3 types based on donor source: live related donor (procedure code 00.91), live nonrelated donor (procedure code 00.92) or cadaver (procedure code 00.93). CMS also identified cases without a donor source. The cases with the live related donor source had the lowest average cost and shortest length of stay and the cases without a transplant donor source procedure code had the highest average costs and longest length of stay. CMS does not believe it is appropriate to include these transplants without a donor source with the live nonrelated or cadaver donor cases, because this would encourage providers not to report the transplant donor source code. Further, since approximately one-quarter of the cases did not provide a transplant donor source, CMS considers the data incomplete.

2. MDC 4 (Diseases and Disorders of the Respiratory System)

Influenza with Pneumonia: CMS received a request during the comment period for the FY 2012 IPPS proposed rule related to reassignment of cases with a combined diagnosis of influenza and pneumonia that was not addressed because CMS considered it out of the scope of the FY 2012 proposed rule. The request was for reassigning cases with a combined diagnosis of influenza and pneumonia from a set of simple pneumonia MS-DRGs (193, 194, and 195) to a set of more severe pneumonia MS-DRGs (177, 178 and 179). As a result of their analysis of the FY 2011 MedPAR file, CMS is proposing to reassign cases with a principal diagnosis code 487.0 (Influenza with pneumonia) and an additional secondary diagnosis code of one of the following pneumonia codes listed as a secondary diagnosis code from MS-DRGs 193, 194, and 195 to MS-DRGs 177, 178, and 179: 482.0, 482.1, 482.40 – 482.42, 482.49, 482.81 – 482.84, and 482.89. CMS invites public comment on this proposal.

3. MDC 5 (Diseases and Disorders of the Circulatory System)

a. Percutaneous Mitral Valve Repair with Implant: CMS received a request to reassign procedure code 35.97 (Percutaneous mitral valve repair with implant) from MS-DRGs that involve percutaneous cardiovascular procedures to a set of MS-DRGs for cardiac valve and other major cardiothoracic procedures, MS-DRGs 216 – 221). CMS is not proposing to reassign procedure code 35.97 and invites public comment.

Based on analysis of FY 2011 MedPAR data, CMS found that most of the cases with procedure code 35.97 were found in MS-DRGs 250 and 251. There were an average of 39 cases in MS-DRG 250 with average costs of $29,753 (including cases with an MCC) and 98 cases in MS-DRG 251 (without MCC) with average costs of $18,651. These average costs are higher than the average costs of other cases assigned to MS-DRGs 250 ($19,673) and 251 ($12,658) but CMS notes they are significantly less than the average costs of cardiac valve

replacement cases assigned to MS-DRGs 216 – 221 (the average cost for MS-DRG 216 was $61,015 and MS-DRG 221 was $29,082).

b. Endovascular Implantation of Branching or Fenestrated Grafts in Aorta: CMS received a request to reassign procedure code 39.78 (Endovascular implantation of branching or fenestrated graft(s) in aorta) that was created for use beginning October 1, 2011 from MS-DRGs 252 – 254 (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively) to MS-DRGs 237 and 238 (Major Cardiovascular Procedures with MCC and without MCC, respectively) because the clinical coherence and consumption of resources were more similar to the major cardiovascular procedures. CMS is not proposing to reassign procedure code 39.78 and invites public comment.

CMS believes that for this new code, which has no data history, the current assignment based on clinical coherence and resource consumption is correct. They will continue to evaluate this procedure. (The requestor also applied for new technology add-on payment. This is discussed in Section II-I.)

4. MDC 10 (Endocrine, Nutritional, and Metabolic Diseases and Disorders)

Disorders of Porphyrin Metabolism: CMS received a request to create a new MS-DRG for cases reporting a principal diagnosis of 277.1 (Disorders of porphyrin metabolism) instead of the current assigned MS-DRG 642 (Inborn and Other Disorders of Metabolism). CMS is not proposing to create a new MS-DRG or to reassign cases reporting a principal diagnosis code of 277.1. They will continue to monitor this issue and determine how to better account for the variation in resource utilization for these cases. CMS invites public comment on this proposal.

CMS analyzed data from the FY 2011 MedPAR file and found 1,447 cases in MS-DRG 642 with an average length of stay of 4.63 days and average costs of $7,400. Within this MS-DRG, they found 330 cases with diagnosis 277.1; these cases had an average length of stay of 6.12 days and average costs of $11,476. These costs include treating patients with acute intermittent porphyria with intravenous injection of hemin. CMS determined that these findings, including the small volume of cases, do not support the creation of a new MS-DRG. CMS also explored an alternative option of reassigning principal diagnosis code 277.1 to MS-DRGs 643-645. Analysis of data from the MedPAR file did not support this reassignment and CMS' clinical advisors did not support this reassignment.

5. Proposed Medicare Code Editor (MCE) Changes

The Medicare Code Editor (MCE) is a software program that detects and reports errors in the coding of Medicare claims data. Patient diagnoses, procedure(s), and demographic information are entered into the Medicare claims processing systems and are subjected to a series of automated screens. The MCE screens are designed to identify cases that require further review before classification into a MS-DRG. For FY 2013, CMS is proposing to make a change to the MCE edits which includes the creation of a new length of stay edit for continuous invasive mechanical ventilation for 96 consecutive hours or more.

Length of stay edit for continuous invasive mechanical ventilation for 96 consecutive hours or more: CMS proposes a new edit in which claims found to have procedure code 96.72 (Continuous invasive mechanical ventilation for 96 consecutive hours or more) with a length of stay less than 4 days would be returned to the provider for validation and resubmission. A change request with instructions would be issued prior to the implementation date. CMS invites comments on this proposal which would be effective FY 2013.

CMS analyzed the FY 2011 MedPAR data to determine how many cases reported procedure code 96.72 with a length of stay less than 4 days. CMS found a total of 595 cases: 89 cases with a length of stay of 1 day and average costs of $5,984, 134 cases with a length of stay of 2 days and average costs of $7,776, and 372 cases with a length of stay of 3 days and average costs of $11,613. The data also demonstrated that the 595 cases were distributed across a wide range of MS-DRGs. The two MS-DRGs with the highest volume of cases reporting procedure code 96.72 and having a length of stay less than 4 days were MS-DRG 207 and 870 and CMS notes that both of these MS-DRGs specifically reference "96+ hours" in their titles. CMS notes that a total of 245 cases were grouped to MS-DRGs 207 and 870 in error, resulting in approximately $25,000 in increased payments for each case (or approximately $6 million in increased payments for all 245 cases). CMS states these overpayments justify the proposed edit. CMS also acknowledges that there are particular circumstances, such as patients who may require observation services, where procedure code 96.72 is appropriately reported on the claim with a length of stay less than 4 days.

6. Surgical Hierarchies

The surgical hierarchy, an ordering of surgical classes from most resource intensive to least resource intensive, performs as a decision rule within the GROUPER under which cases are assigned to a single DRG when an inpatient stay entails multiple surgical procedures, each one of which, occurring by itself, could result in assignment of the case to a different DRG within the MDC to which the principal diagnosis is assigned. Application of this hierarchy ensures that cases involving multiple surgical procedures are assigned to the DRG associated with the most resource intensive surgical class.

For FY 2013, CMS is proposing limited changes to the MS-DRG classification and is not proposing any changes to the surgical hierarchy for the Pre-MDCs and MDCs for FY 2013.

7. Complications or Comorbidity (CC) Exclusions List

CMS created the CC Exclusions List in 1987 to: (1) preclude coding of CCs for closely related conditions; (2) preclude duplicative or inconsistent coding from being treated as CCs; and (3) ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair. For FY 2013, CMS is not proposing to make any revisions to the CC Exclusion list.

Suggested Changes to the MS-DRG Severity Levels for Diagnosis Codes for FY 2013

a. *Protein-Calorie Malnutrition:* CMS received a request to change the severity level for three protein-calorie nutrition diagnosis codes: 263.0 (Malnutrition of moderate

degree), 263.1 (Malnutrition of mild degree), and 263.9 (Unspecified protein-calorie malnutrition). Specifically, the request was to change the severity level for diagnosis codes 263.0 and 263.1 from a non-CC to a CC and change the severity level for diagnosis code 263.9 from a CC to a non-CC. Based on data from the FY 2011 MedPAR file and clinical analysis, CMS is proposing for FY 2013 to change diagnosis codes 263.0 and 263.1 from a non-CC to a CC. CMS is not proposing any change to the severity level for diagnosis code 263.9. Public comments are accepted.

b. *Antineoplastic Chemotherapy Induced Anemia:* CMS received a request to change the severity level for diagnosis code 285.3 (Antineoplastic chemotherapy induced anemia) from a non-CC to a CC. Based on analysis of data from the FY 2011 MedPAR file and clinical analysis, CMS is not proposing any changes to the severity level for this diagnosis code. Public comments are accepted.

c. *Cardiomyopathy and Congestive Heart Failure, Unspecified:* CMS received a request to change the severity level for diagnosis code 428.0 (Congestive heart failure, unspecified) from a non-CC to a CC. CMS examined claims data in the FY 2011 MedPAR file for this diagnosis code and determined that the data do not consistently support a change in the severity codes. CMS' clinical advisors did not support proposing any changes to the severity level, indicating that the diagnosis code is very nonspecific and does not identify the severity of the heart failure. CMS is not proposing any changes to the severity level for this code. Public comments are accepted.

d. *Chronic Total Occlusion of Artery of the Extremities:* CMS received a request to change the severity level for diagnosis code 440.4 (Chronic total occlusion of artery of the extremities) from a non-CC to a CC. Based on analysis of data from the FY 2011 MedPAR file and clinical review, CMS is proposing to change the severity level for diagnosis code 440.4 from a non-CC to a CC. Public comments are accepted.

e. *Acute Kidney Failure with Other Specified Pathological Lesion in Kidney:* CMS received a request to change the MCC severity level for diagnosis code 584.8 (Acute kidney failure with other specified pathological lesion in kidney). Based on analysis of data from the FY 2011 MedPAR file and clinical analysis, CMS is proposing to change the severity level of this diagnosis code from a MCC to a CC. Public comments are accepted.

f. *Pressure Ulcer, Unstageable:* CMS received a request to change the severity level for diagnosis code 707.25 (Pressure ulcer, unstageable) from a non-CC to a MCC. CMS examined claims data in the FY 2011 MedPAR file and the analysis were more supportive of a CC than a MCC. CMS' clinical advisors did not support changing the severity of this diagnosis code because an unstageable pressure ulcer is not a stage III or IV ulcer and should continue to be classified as a non-CC. CMS is not proposing any change. Public comments are accepted.

A complete updated MCC, CC, and Non-CC Exclusions List is available through the CMS Web site at: http://www.cms.hhs.gov/AcuteInpatientPPS.

8. Review of Procedure Codes in MS DRGs 981 through 983; 984 through 986; and 987 through 989

Each year, CMS reviews cases assigned to former CMS DRG 468 (Extensive O.R. Procedure Unrelated to Principal Diagnosis), CMS DRG 476 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis), and CMS DRG 477 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis) to determine whether it would be appropriate to change the procedures assigned among these CMS DRGs. Under the MS-DRGs that CMS adopted for FY 2008, CMS DRG 468 was split three ways and became MS-DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). CMS DRG 476 became MS-DRGs 984, 985, and 986 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). CMS DRG 477 became MS-DRGs 987, 988, and 989 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively).

For FY 2013, CMS is not proposing any changes to the procedures assigned among these MS-DRGs.

9. Proposed Changes to the ICD-9-CM Coding System, Including Discussion of the Replacement of the ICD-9-CM Coding System with the ICD-10-CM and ICD-10-PCS Systems in FY 2014

A proposed rule (CMS-0040-P) published on April 17, 2012 would delay the implementation of the ICD-10 coding system applicable to hospital inpatient services from October 1, 2013 to October 1, 2014. The comment period for this proposed rule closes on May 17, 2012.

a. ICD-9-CM Coding System: For FY 2013, there were no changes to the ICD-9-CM coding system due to the partial code freeze because of the planned implementation of the ICD-10 coding system on October 1, 2013. Consequently, there are no new, revised, or deleted diagnosis and procedure codes.

b. Code Freeze: In the January 16, 2009 ICD-10-CM and ICD-10-PCS final rule, there was a discussion of the need for a partial or total freeze in the annual updates to both ICD-9-CM and ICD-10-CM and ICD-10-PCS codes. After multiple public meetings and opportunities for public comment, CMS announced at the September 15-16, 2010 and September 13, 2011 ICD-9-CM Coordination and Maintenance Committee meetings that a partial freeze of both ICD-9-CM and ICD-10 codes would be implemented as follows:

- The last regular annual update to both ICD-9-CM and ICD-10 code sets was on October 1, 2011.
- On October 1, 2012, there will be only limited code updates to both ICD-9-CM and ICD-10 code sets to capture new technology and new diseases.
- On October 1, 2013, there will be only limited code updates to ICD-10 code sets to capture new technology and diagnosis. There were to be not updates to the ICD-9-CM, as the system would no longer be a HIPAA standard.
- On October 1, 2014, regular updates to ICD-10 will begin.

If the compliance date of ICD-10 is delayed from October 1, 2013 to October 1, 2014, CMS revises the implementation as follows:

- On October 1, 2014, there will be only limited code updates to ICD-10 code sets to capture new technology and diagnosis. There will not be any updates to the ICD-9-CM, as the system will no longer be a HIPAA standard.
- On October 1, 2015, regular updates to ICD-10 will begin.

CMS notes the ICD-9-CM Coordination and Maintenance Committee will continue to meet twice a year.

c. Processing of 25 Diagnosis Codes and 25 Procedure Codes on Hospital Inpatient Claims: CMS will continue to process up to 25 diagnosis codes and 25 procedure codes when received on the 5010 format.

d. ICD-10 MS-DRGs: CMS plans to post the final version of the ICD-10 MS-DRGs which will be subject to notice and comment rulemaking. They will provide updated information on this activity through the ICD-9-CM Coordination and Maintenance Committee.

During FY 2012, CMS finalized the ICD-10 MSG-DRGs Version 29.0 and posted a Definitions Manual of ICD-10 MS-DRGs Version 29.0 on the CMS ICD-10 MS-DRG Web site. CMS also posted a paper , "Impact of the Transition to ICD-10 on Medicare Inpatient Hospital Payments" on the CMS web site at http://www.cms.goc/ICD10/17_ICD10_MS_DRG_Conversion_Project.asp.

F. Recalibration of MS-DRG Weights

The Secretary is required by statute to revise the DRG groups and weights annually to reflect changes in technology, medical practice, and other factors. In developing relative weights for the FY 2013 proposed rule, CMS used two data sources:

- FY 2011 MedPAR data for discharges occurring on October 1, 2009, through September 30, 2010, based on bills received by CMS through December 31, 2010, from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which are under a waiver from the IPPS under section 1814(b)(3) of the Act). The FY 2011 MedPAR file used in calculating the proposed relative weights includes data for approximately 10.4 million Medicare discharges from IPPS providers. Discharges for Medicare beneficiaries enrolled in a Medicare Advantage managed care plan are excluded from the analysis. The data also exclude CAHs, including hospitals that subsequently became CAHs after the period from which the data were taken; and

- Medicare cost report data files from HCRIS, principally for FY 2010 cost reporting periods (that is, cost reporting periods beginning on or after October 1, 2009, and before October 1, 2010). FY 2010, which precedes the start of FY 2013 by three years, typically would represent the most recent full set of cost report data available. CMS found, however, that cost reports in the FY 2010 HCRIS data with fiscal year start dates that are on or after May 1, 2010, and before October 1, 2010, are not accessible because they were filed on the new cost report Form 2552-10, and cost reports filed on Form

2552-10 are not currently accessible in the HCRIS. To assure adequate data for calculating the relative weights, CMS proposes to calculate the FY 2013 MS-DRG relative weights with data from FY 2010 cost reports for providers with fiscal year begin dates of on or after October 1, 2009 and before May 1, 2010, and to backfill with data from FY 2009 cost reports for those providers that have fiscal year begin dates on or after May 1, 2010 through September 30, 2010. CMS used cost report data for the December 31, 2011 update of the HCRIS for FY 2009 and FY 2010 in calculating the proposed FY 2013 relative cost-based weights.

Adhering to the process used to calculate the weights for FY 2012, charges were converted to costs using national average CCRs. The resulting 15 national average CCRs used for the FY 2013 proposed rule are shown in the table below (for comparison, the FY 2012 final rule CCRs also are shown):

Group	**CCR FY 2012 Final Rule**	**CCR FY 2013 Proposed Rule**
Routine Days	0.539	0.514
Intensive Days	0.473	0.442
Drugs	0.202	0.199
Supplies & Equipment	0.345	0.335
Therapy Services	0.403	0.370
Laboratory	0.155	0.142
Operating Room	0.272	0.238
Cardiology	0.169	0.145
Radiology	0.152	0.136
Emergency Room	0.263	0.226
Blood and Blood Products	0.415	0.389
Other Services	0.416	0.397
Labor & Delivery	0.470	0.451
Inhalation Therapy	0.200	0.189
Anesthesia	0.128	0.109

The new cost-based relative weights were normalized by an adjustment factor of 1.5877342556 so that the average case weight after recalibration is equal to the average case weight before recalibration. The normalization adjustment is intended to ensure that recalibration by itself neither increases nor decreases total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act.

G. Proposed Add-On Payments for New Services and Technologies

1. Background

The new medical service or technology add-on payment policy provides additional payments for cases with high costs involving eligible new medical services or technologies. To qualify, services must be new, more costly than existing technology, and represent a substantial clinical improvement. CMS first determines whether a

medical service or technology meets the newness criteria before making a determination about cost and substantial clinical improvements.

Current regulations provide that "a medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD-9-CM code assigned to the new medical service or technology (depending on when a new code is assigned and data on the new medical service or technology become available for DRG recalibration). CMS does not consider a service or technology to be new if it is substantially similar to one or more existing technologies. That is, even if a technology receives a new FDA approval, it may not necessarily be considered "new" for purposes of new technology add-on payments if it is "substantially similar" to a technology that was approved by FDA and has been on the market for more than 2 to 3 years. In determining substantial similarity, CMS considers: (1) whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; (2) whether a product is assigned to the same or a different DRG; and (3) whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population. If all three components are present and the new use is deemed substantially similar to one or more of the existing uses of the technology, CMS would conclude that the technology is not new and, therefore, not eligible for the new technology add-on payment.

Under the cost criterion, to assess the adequacy of payment for a new technology paid under the applicable MS-DRG prospective payment rate, CMS evaluates whether the charges for cases involving the new technology exceed certain threshold amounts. CMS applies "a threshold...that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges) or 75 percent of one standard deviation for the diagnosis-related group involved." Table 10 that was included in the FY 2012 IPPS/LTCH PPS final rule contains the final thresholds that will be used to evaluate applications for new technology add-on payments for FY 2013 (http://www.cms.gov/AcuteInpatientPPS/FR2012/list.asp - TopOfPage).

Under the third criterion, current regulations provide that a new technology is an appropriate candidate for an additional payment when it represents "an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries." For example, a new technology represents a substantial clinical improvement when it reduces mortality, decreases the number of hospitalizations or physician visits, or reduces recovery time compared to the technologies previously available.

CMS also requires that all applicants for new technology add-on payments must have FDA approval for their new medical service or technology by July 1 of each year prior to the beginning of the fiscal year that the application is being considered.

For an approved new technology, if the costs of the discharge (determined by applying cost to charge ratios) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to

the lesser of: (1) 50 percent of the estimated costs of the new technology (if the estimated costs for the case including the new technology exceed Medicare's payment); or (2) 50 percent of the difference between the full DRG payment and the hospital's estimated cost for the case. Unless the discharge qualifies for an outlier payment, Medicare payment is limited to the full MS-DRG payment plus 50 percent of the estimated costs of the new technology. Add-on payments for new medical services or technologies for FY 2005 and later years are not subjected to budget neutrality.

Applicants for add-on payments for new medical services or technologies for FY 2014 must submit a formal request, including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement, along with a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. Complete application information, along with final deadlines for submitting a full application, will be posted as it becomes available on the CMS Web site at: http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp.

2. Public Input Before Publication of a Notice of Proposed Rulemaking on Add-On Payments

In order to provide an opportunity for public input regarding add-on payments for new medical services and technologies for FY 2012, CMS held a town hall meeting on February 14, 2012. Four of the five FY 2013 applicants presented information on their respective technology, including a discussion of data reflecting the substantial clinical improvement aspect of the technology. In their evaluations, CMS considered the applicants' presentation made at the town hall meeting and written comments received by March 6, 2012.

3. FY 2013 Status of Technologies Approved for FY 2012 Add-On Payments

AutoLaser Interstitial Thermal Therapy (AutoLITT™) System: AutoLITT™, is a minimally invasive, MRI-guided laser tipped catheter designed to destroy malignant brain tumors with interstitial thermal energy causing immediate coagulation and necrosis of diseased tissue. CMS is not proposing to continue making new technology add-on payments for the AutoLITT™ in FY 2013. CMS notes that in "close proximity" to publication of this proposed rule, the manufacturer provided information on the delayed market release of the product and CMS anticipates receiving further information on the delayed market release date from the manufacturer. CMS invites public comment on this proposal.

CMS states that their practice has been to begin and end new technology add-on payments on the basis of a fiscal year; they have generally followed a guideline that uses a 6-month window before and after the start of the fiscal year to determine whether or not to extend the new technology add-on payment for an additional fiscal year. In general, they extend add-on payments for an additional year only if the 3-year

anniversary date of the product's entry on the market occurs in the latter half of the fiscal year (70 FR 47362).

Monteris Medical submitted an application for new technology add-on payments for FY 2011 for the AutoLITT™. AutoLITT™ received a 510K FDA clearance in May 2009. The application for new-technology add-on payments indicated the technology was actually introduced to the market in December 2009 and in supplementary application information the company indicated that the first sale of the product took place on March 19, 2010. CMS considers the beginning of the newness period for the device to commence from the market release date of December 2009. Therefore, for FY 2013, as of December 2012 the AutoLITT™ will have been on the market for 3 years and thus not be considered "new" nor be considered eligible for new technology add-on payments in FY 2013. In close proximity to the publication of this proposed rule, the manufacturer provided CMS with information that the market release date of AutoLITT ™ occurred after April 2010 (which occurs in the latter half of the fiscal year) and therefore, it appears that the device would still be considered "new" for FY 2013 and would still be eligible for new technology add-on payments in FY 2013.

4. FY 2013 Applications for New Technology Add-On Payments

CMS received six applications for new technology add-on payments for FY 2013; two applicants withdrew their applications prior to the publication of this proposed rule.

a. Glucarpidase (Trade Brand Voraxaze®): BTG International, Inc. submitted an application for the new technology add-on payments for Glucarpidase for FY 2013. Glucarpidase is used in the treatment of toxic methotrexate (MTX) concentrations as a result of renal impairment.

Newness Criterion
Voraxaze® is an orphan drug that received FDA approval on January 17, 2012. Beginning in 1993, certain patients could obtain expanded access for treatment using Voraxaze® as an investigational drug and since 2007, the company has been authorized to recover the costs of making Voraxaze® available through its expanded access program. The company plans to make the drug available on the market as a commercial product to the larger population in April 2012. The request for a new procedure code, was discussed at the ICD-9-CM Coordination and Maintenance Committee's March 2012 meeting; information regarding the code proposal is at http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html.

CMS is concerned that Voraxaze® may no longer be considered "new". Although they generally believe that the newness period begins on the date that FDA approval is granted, which for Voraxaze® is January 2012, they note that the applicant has been authorized to recover certain costs of making Voraxaze® available through its expanded access program since 2007 and is concerned that the cost of the drug is already reflected within the MS-DRG relative weights.

CMS notes that they have concluded that technologies with Humanitarian Device Exemption (HDE) approval may be eligible for new technology add-on payments. CMS believes that HDE approval constitutes FDA approval in the context of the newness criterion and this approval would begin the start of the newness period, subject to market availability. In this propose rule, CMS compares the processes and standards for providing expanded access to investigational drugs for treatment use and the HDE program and discusses similarities and differences that are relevant to the newness criterion. CMS concludes that the FDA is not granting FDA approval when it authorizes expanded access to an investigational drug. Thus, when evaluating whether Voraxaze® meets the newness criterion, it may not be appropriate to consider the date when Voraxaze® became available to certain patients through the applicant's expanded access program as the date of market availability.

CMS invites public comment on whether a drug is considered "new" for the purposes of new technology add-on payments starting with its availability in the expanded access program, and how that may differ from devices considered "new" starting from the date the device received FDA approval under a HDE, subject to market availability or availability to Medicare beneficiaries. They also invite public comment on whether any unapproved investigational drug for which cost recovery is authorized are already included in data used to determine relative weights and how this influences the start of a newness period, if at all. In addition, CMS also invites public comments on these issues as they relate to Voraxaze® and on the market availability of Voraxaze® between its FDA approval date of January 17, 2012 and the application market availability date of April 2012.

Cost Criterion

For its cost analysis, the applicant researched the 2009 Standard Analytic Inpatient File for cases with a principal or secondary diagnosis of osteosarcoma, acute lymphoblastic leukemia, non-Hodgkin's lymphoma, or primary CNS lymphoma with a corresponding procedure code for chemotherapy (99.25) that may be eligible for Voraxaze® based on the product's approved indications. This search yielded potentially eligible cases within 249 MS-DRGs, of which 56 MS-DRGs captured 12 or more cases. Using the universe of cases (249 MS-DRGs), the applicant added the additional costs of Voraxaze® to the case-weighted average standardized charge per case but they did not convert the costs to charges because of the drug's high cost. The applicant noted that the cost of the technology was proprietary information.

The applicant compares the average case-weighted standardized charge per case (including the cost of Voraxaze®) to the average case-weighted threshold and concludes that Voraxaze® meets the cost criterion. Specifically, within the 249 MS-DRGs, for 12,324 eligible cases the case-weighted average standardized charge per case was $87,582 with a case-weighted threshold of $39,216. Excluding MS-DRGs with fewer than 11 cases resulted in 12,134 eligible cases within 56 MS-DRGs. These cases have a case-weighted average standardized charge per case of $84,039 with a case-weighted threshold of $37,195. The applicant also analyzed the 20 MS-DRGs that

contained the highest number of cases and based on the 20 cases identified, determined a case-weighted average standardized charge per case of $80,400 with a case-weighted threshold of $34,990.

CMS invites public comment on whether Voraxaze® meets the cost criterion. They are also interested in comments about the methodologies used in this analysis, including (1) the methods used to identify the eligible cases used in the cost analysis, especially if there are cases that should be excluded because of clinical reasons, and if there are other ways to identify cases for which this technology may be appropriate, and (2) the appropriateness of not converting the costs to charges and what would be an accurate and appropriate CCR for this technology.

Substantial Clinical Improvement Criterion
The application states that Voraxaze® is a clinical improvement compared to current treatment because it is less time intensive, allows certain patient populations to avoid risks associated with current treatment options (extracorporeal methods), and has characteristics that allow it to reduce MTX concentrations more effectively. The applicant provided the results from a study of 23 patients diagnosed with MTX-induced renal dysfunction treated with Voraxaze® and additional published peer-reviewed articles relevant to their application to support their assertion that they meet the substantial clinical improvement criteria. CMS invites comments on whether Voraxaze® meets the criterion of representing a substantial clinical improvement for Medicare beneficiaries.

b. DIFICID™ (Fidaxomicin) Tablets: Optimer Pharmaceuticals, Inc. submitted an application for the new technology add-on payments for DIFICID™ (Fidaxomicin) for FY 2013. According to the company, Fidaxomicin is a major clinical advancement in treatment of *Clostridium difficile*-associated diarrhea (CDAD). As indicated on the labeling submitted to the FDA, Fidaxomicin is taken twice a day as a daily dosage as an oral antibiotic.

Newness criterion
Fidaxomicin was approved by the FDA on May 27, 2011 for the treatment of CDAD in adult patients, 18 years of age and older and was commercially available on the market within 7 weeks after the FDA approval was granted. CMS states there aren't any ICD-9-CM diagnosis or procedure codes that exist to uniquely identify the use of Fidaxomicin, or any oral drug, as a procedure. Optimer's request for a new ICD-9-CM procedure code was discussed at ICD-9-CM Coordination and Maintenance Committee's March 5, 2012 meeting (The web site link is provided in the previous Voraxaze® discussion).

CMS discusses that under their current new technology add-on payment policy, eligibility for consideration for new technology add-on payments is limited to new technologies associated with procedures described by ICD-9-CM codes. CMS established the framework for this current policy in the FY 2002 IPPS final rule (66 FR 46907 through 46915). Accordingly, CMS does not consider drugs that are only taken

orally to be eligible for consideration for new technology add-on payments, because there is no procedure code associated with these drugs, and therefore, no ICD-9-CM code(s). CMS notes that this interpretation is also consistent with other Medicare payment policies and notes that when drugs taken orally are part of an outpatient encounter, they would likely be considered self-administered drugs under the Hospital Outpatient Prospective Payment System (OPPS). For example, if a beneficiary were subsequently admitted to the hospital within three days of an outpatient visit where they were prescribed self-administered drugs, the hospital would not include these self-administered drugs on the inpatient bill because they are self-administered drugs and not covered under the OPPS. CMS invites public comment on their interpretation of this policy regarding drugs that are only self-administered for consideration for new technology add-on payments. They also invite comments on whether or not Fidaxomicin meets the newness criterion.

Cost Criterion

For its cost analysis, the applicant researched the FY 2010 MEdPAR file for cases that would be eligible for treatment with Fidaxomicin. They identified cases in which a patient had been diagnosed with CDAD by searching the MedPAR file for claims that included ICD-9-CM diagnosis code 008.45 (Intestinal infection due to *Clostridium difficile*) as a principal or secondary diagnosis and provided three examples to demonstrate that the drug meets the cost criterion. In the analysis, the applicant submitted data related to the estimated cost and charge of a 10-day dosage of the drug, using a charge markup. The applicant has not released the cost of the drug, asserting it is proprietary information.

In the first analysis, the applicant researched the diagnosis code across all MS-DRGs and found 162,310 cases within 536 MS-DRGs and determined a case-weighted average standardized charge per case (excluding charges for the cost of Fidaxomicin) of $50,136. Using a factor of 6.5 percent to inflate the charges to 2012 rates based on the Medical Consumer Price Index (CPI), the case-weighted standardized charge per case was $53,394 and after adding the charges related to the technology to the inflated charges, the applicant determined a final case-weighted average standardized charge per case of $58,994. The case-weighted threshold was $43,673 and the applicant maintains that Fidaxomicin meets the cost criterion.

In the second analysis, the applicant only included those cases with the diagnosis code 008.45 only as the principal diagnosis and mapped to the MS-DRGs 371, 372, and 373 (Major Gastrointestinal Disorders and Peritoneal Infections with MCC, with CC, and without CC/MCC respectively) and identified 55,410 cases. Using the same methodology, the applicant determined a final case-weighted average standardized charge per case of $35,428 with a case-weighted threshold of $34,730. In the third analysis, the applicant only included those cases with the diagnosis code 008.45 only as the principal diagnosis across all MS-DRGs and then narrowed the results of the analysis to include only the top 37 MS-DRGs (in volume of cases), which accounted for 75 percent of all cases. This analyses resulted in 121,748 cases. Using the same

methodology, the applicant determined a final case-weighted average standardized charge per case of $54,082 with a case-weighted threshold of $42,452.

CMS invites public comment on whether or not Fidaxomicin meets the cost criterion. They are also interested in comments about the methodologies used in this analysis, in particular the assumptions made about the dosage in developing the cost analysis. CMS is concerned that these analyses assume that the drug might not be administered during the duration of the inpatient stay and might be prescribed and self-administered before or after being discharged from the hospital. They are also concerned that the estimates do not remove charges that describe other treatment options such as Vancomycin, since use of these treatments would preclude the use of Fidaxomicin. CMS is also interested in comments about the applicant's selection of claims with a diagnosis code 008.45 and whether those cases accurately represent the Medicare population that may benefit from this drug.

Substantial Clinical Improvement Criterion,
The applicant states that Fidaxomicin represents the first major clinical advancement in the treatment options available to address CDAD in more than 25 years and is one of only two agents indicated by the FDA to treat this condition.

The applicant reported on two randomized, double-blinded trials. A non-inferiority design was utilized to demonstrate the efficacy of administering Fidaxomicin compared to administering Vancomycin to adult patients with CDAD. According to the applicant, clinical success at the end of treatment and mortality rates were similar across both treatments but that Fidaxomicin is superior to Vancomycin for sustaining a clinical response beyond 25 days after the end of treatment. The applicant also states that the effects of administering Fidaxomicin has minimal impact on normal gut flora due to its limited specificity and could be associated with a lower risk of developing vancomycin-resistent Enterococcus. They also assert that Fidaxomicin has the potential to decrease hospitalizations and physician office visits, as well as to improve the quality of life for these patients.

CMS states they are concerned that this technology may not offer a substantial clinical improvement compared to other effective treatment alternatives for patients with CDAD. They are also concerned about the long-term possibility that patients may develop resistance to this drug since the applicant did not provide any data substantiating their claim that there is no significant clinical resistance developing with the use of the drug. CMS invites public comment on whether or not Fidaxomicin meets the substantial clinical improvement criterion based on the information provided by the applicant.

c. Zilver® PTX® Drug Eluting Stent: Cook® Medical submitted an application for new technology add-on payments for the Zilver® PTX® Drug Eluting Stent (Zilver® PTX®) for FY 2013. This technology is used for the treatment of peripheral artery disease (PAD) of superficial femoral arteries (SFA). The applicant indicates that the

stent is self-expanding, made of nitinol (nickel titanium), and is coated with the drug Paclitaxel (Paclitaxel is approved for use as an anticancer drug and for use with coronary artery stents to reduce the risk of renarrowing of the coronary arteries after the stenting procedure).

Newness Criterion
The applicant states there are currently no FDA approved drug-eluting stents for the superficial femoral arteries and expects to receive FDA approval for the stent in the second quarter of 2012. The technology is currently described by ICD-9-CM procedure code 00.60 (Insertion of drug-eluting stent(s) of the superficial femoral artery). CMS invites comments about how Zilver® PTX® meets the newness criterion.

Cost Criterion
For its cost analysis, the applicant searched the FY 2009 MedPAR file for cases with procedure code 39.90 (Insertion of non-drug-eluting peripheral vessel stents) in combination with diagnosis codes 440.20 through 440.24 (codes indicating a diagnosis related to atherosclerosis of the extremities) mapped to MS-DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, CC and without CC/MCC, respectively). The applicant found 7,144 (or 24.4 percent of all cases) in MS-DRG 252; 9,146 cases (or 31.2 percent of all cases) in MS-DRG 252; and 13,012 cases (or 44.4 percent of all cases) in MS-DRG 254. The case-weighted average charge per case was $60,236. This case-weighted average charge include the charges related to the non-drug-eluting stent and do not include charges related to the Zilver® PTX®.

The applicant used two methodologies to remove the charges of the non-drug-eluting stent and replace them with the charges related to the Zilver® PTX® stent. CMS notes that although the applicant submitted data related to the estimated cost of the non-drug-eluting peripheral vessel stents and the Zilver® PTX® stent, the applicant noted that the cost of these devices was proprietary information. In the first methodology, the number of stents per case was based on the ICD-9-CM codes on each claim: 00.45 (Insertion of one vascular stent), 00.46 (Insertion of two vascular stents), 00.47 (Insertion of three vascular stents) and 00.48 (Insertion of four or more vascular stents) with the applicant assuming a maximum of four stents per case. The applicant multiplied the amount of stents used per case by the average market price for non-drug-eluting peripheral vessel stents and then converted the cost of the stents per case to a charge by dividing the results by the national average CCR of 0.329 for supplies and equipment (76 FR 51571). To inflate the charges from FY 2009 to FY 2012, the applicant inflated the average standardized charge per case with an inflation factor of 6 percent. For the Zilver® PTX® stent calculations, the applicant used data from the Zilver® PTX® Global Registry Clinical Study which indicated an average of 1.9 stents per case. The applicant followed the same methodology and multiplied the average of 1.9 stents used per case by the future market price for the Zilver® PTX® and then converted the cost of the stents used per claim to a charge by dividing the results by the national CCR for supplies and equipment. The amount of charges related to the Zilver® PTX® was added to the inflated average standardized charge per case and determined a final case-weighted average standardized charge per case of $60,014.

Using the FY 2013 Table 10 thresholds, the case-weighted threshold for MS-DRGs 252, 253, and 254 was approximately $52,293 and the applicant maintains that their product meets the cost criterion.

The second methodology was similar to the first methodology but the applicant used hospital-specific CCR from the FY 2009 IPPS impact file to convert the cost of the non-drug-eluting peripheral vessel stents and the cost of the Zilver® PTX® to charges. Using this methodology (described in greater detail in the proposed rule), the applicant determined a final case-weighted average standardized charge per case of $60,339 for cases with the Zilver® PTX®. The case-weighted threshold for MS-DRGs 252, 253, and 254 was approximately $52,293 and the applicant again maintains that their product meets the cost criterion.

CMS invites public comment on whether or not the Zilver® PTX® meets the cost criterion. They also are interested in comments on the methodologies used by the applicant in its analysis, including its assumptions regarding the types of cases in which this technology could be used, the number of stents required for each case, and the CCRs used in the cost calculations.

Substantial Clinical Improvement Criteria

The applicant shared several findings from the clinical trial data to demonstrate that Zilver® PTX® meets the substantial clinical improvement criterion. The applicant asserts that their product decreases the recurrence of symptoms arising from restenotic SFA lesions, the rate of subsequent diagnostic or therapeutic interventions required to address restenotic lesions, and the number of future hospitalizations.

The applicant cited a 480-patient, multicenter, multinational randomized controlled trial that compared the Zilver® PTX® to balloon angioplasty. An additional component of the study allowed a direct comparison of the Zilver® PTX® to a bare metal Zilver® stent. The primary safety endpoint of the trial was "Event-Free Survival" (EFS), defined as "freedom from the major adverse events of death, target lesion revascularization, target limb ischemia requiring surgical intervention or surgical repair of the target vessel, and freedom of worsening systems as described by the Rutherford classification by 2 classes or to class 5 or 6." The primary effectiveness endpoint was primary patency, defined as less than 50 percent renarrowing. The applicant stated that the Zilver® PTX® is as safe or safer than balloon angioplasty based on the finding that the Zilver® PTX® had an EFS of 90.4 compared to an EFS of 83.9 percent for balloon angioplasty. In addition, the Zilver® PTX® demonstrated a 50-percent reduction in restenosis rate compared to angioplasty and a 20-percent reduction compared to bare metal stents. The applicant also noted that the 12-month patency rate for the Zilver® PTX® compared favorably to the balloon angioplasty patency rate.

The applicant also cited a prospective, multicenter, multinational 787-patient single arm study on the Zilver® PTX® that demonstrated similar safety and effectiveness results that are consistent with the randomized controlled studies. The applicant cited an EFS for the Zilver® PTX® of 89.0 percent and an 86.2 percent primary patency rate.

CMS invites public comment regarding whether the Zilver® PTX® meets the substantial clinical improvement criterion.

d. Zenith® Fenestrated Abdominal Aortic Aneurysm (AAA) Endovascular Graft:
Cook® Medical submitted an application for new technology add-on payments for the Zenith® Fenestrated AAA Endovascular Grant (Zenith® F. Graft) for FY 2013. This technology is an implantable device designed to treat patients with an AAA and are anatomically unsuitable for treatment with currently approved AAA endovascular grafts because of the length of the infrarenal aortic neck. The Zenith® F. Graft is custom-made for each patient and is a modular system consisting of three components.

Newness Criterion
The Zenith® F. Graft was granted FDA approval on April 4, 2012. The technology is described by ICD-9-CM procedure code 39.78 (Endovascular implantation of branching or fenestrated graft(s) in aorta), which became effective October 1, 2011. The procedure code 39.78 maps to MS-DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without MCC/CC, respectively). (As discussed in section II-G, the applicant requested the procedure code 39.78 should map to MS-DRGs 237 and 238 (Major Cardiovascular Procedures with MCC and without MCC, respectively). CMS does not support this reassignment.)

CMS invites public comment regarding whether the Zenith® F. Graft meets the newness criterion for new technology add-on payment.

Cost Criterion
For its cost analysis, the applicant used clinical trial data and three separate analyses of FY 2010 MedPAR data to demonstrate that the Zenith® F. Graft meets the cost criteria. The clinical trial data was based on 173 claims (all Medicare patients except one patient). The analysis found 35 cases (or 20.2 percent of all cases) mapped to MS-DRG 252, 86 cases (49.7 percent of all cases) mapped to MS-DRG 253, and 52 cases (30.1 percent of all cases) mapped to MS-DRG 254, equating to a case-weighted average charge per case of $87,733.

The applicant, however, noted that the investigational devices sold to the trial sites were at reduced prices and the average charge per case contains these reduced charges and not the commercial charges. Thus, the applicant removed the reduced charges for the investigational devices and replaced them with commercial charges, in order to determine the cost of the investigational devices. CMS notes that although the applicant submitted data related to the estimated cost of the investigational devices, the applicant noted that the cost of these devices was proprietary information.

To remove the reduced charges for the investigational devices, the applicant searched the clinical trial claims data (ranging from 2002 to 2010) and removed those charges with a revenue code of 0624 (investigational device exempt). Depending on the year of the claim, using data from the Bureau of Labor Statistics (BLS) Consumer Price Index,

an inflation factor ranging from 3 percent to 27 percent was applied. To determine the amount of commercial charges related to the investigational devices, the applicant divided the cost of the investigational devices by the hospital-specific CCR from the FY 2012 IPPS Final Rule Impact File. After adding the charges of the investigational devices to the inflated charges, the applicant then standardized the charges on each claim and determined a final case-weighted average standardized charge per case of $122,821. Using the FY 2013 Table 10 thresholds, the case-weighted threshold for MS-DRGs 252, 253, and 254 was approximately $53,869. CMS notes that the applicant also conducted a similar cost analysis with drug eluting renal stents instead of bare metal renal stents and obtained similar results. The applicant maintains that the Zenith® F. Graft meets the cost criterion.

The applicant conducted three separate analyses using FY 2010 MedPAR data to identify cases eligible for the Zenith® F. Graft to demonstrate that it meets the cost criterion. Because procedure code 39.78 was effective October 1, 2011, this analysis did not use this code and the applicant searched the MedPAR file for the following three scenarios. The first analysis searched procedure code 39.71 (Endovascular implantation of graft in abdominal aorta) in combination with a diagnosis code of 441.4 (Abdominal aneurysm without mention of rupture). The analysis used MS-DRGs 237 and 238 because procedure code 39.71 maps to these MS-DRGs. The applicant found 1,679 cases (or 9.1 percent of all cases) in MS-DRG 237 and 16,793 cases (or 90.9 percent of all cases) in MS-DRG 238. The case-weighted average charge per case was $81,006. Because these claims data included charges for the existing stent, the applicant removed the amount of charges related to the existing stent graft and replace them with charges for the Zenith® F. Graft. To determine the amount of charges for the existing stent graft, the applicant divided the costs for the existing stent graft by the national average CCR of 0.329 for supplies and equipment (76 FR 51571) and removed the appropriate amount of charges per case from the average charge per case. To inflate the charges from FY 2010 to FY 2012, the applicant used data from the BLS' Consumer Price Index and inflated the case-weighted average standardized charge per case with an inflation factor of 4 percent. The amount of charges for the Zenith® F. Graft was determined by dividing the costs of the graft by the national average of 0.329 for supplies and this number was added to the inflated charges and then standardized. The case-weighted average standardized charge per case was $80,509 and the case-weighted threshold for MS-DRGs 237 and 238, using the FY 2013 Table 10 thresholds, was approximately $72,512. Because the FY 2013 Table 10 thresholds for MS-DRGs 237 and 238 are higher than the thresholds for MS-DRGs 252, 253, and 254, the applicant believes the Zenith® F. Graft meets the cost criterion when compared with MS-DRGs that are mapped to the device.

For the second analysis, the applicant used procedure code 38.44 (Resection of vessel with replacement, aorta) in combination with diagnosis code of 441.4 (Abdominal aneurysm without mention of rupture). Similar to the first analysis, this analysis used MS-DRGs 237 and 238 because the procedure code 39.71 maps to these MS-DRGs. The applicant found 1,310 cases (or 37.9 percent of all cases) in MS-DRG 237 and 2,145 cases (or 62.1 percent of all cases) in MS-DRG 238. The case-weighted average

charge per case was $81,769. The applicant used the same methodology as described above, but removed the amount of charges related to the vascular graft for open procedures and replaced them with the charges for the Zenith® F. Graft. The applicant determined a final case-weighted average standardized charge per case of $118,774. Using the FY 2013 Table 10 thresholds, the case-weighted threshold for MS-DRGs 237 and 238 was approximately $81,776. As above, because the FY 2013 Table 10 thresholds for MS-DRGs 237 and 238 are higher than the thresholds for MS-DRGs 252, 253, and 254, the applicant believes the Zenith® F. Graft meets the cost criterion when compared with MS-DRGs that are mapped to the device.

The third analysis was a combination of the first and second analyses. The applicant used procedure code 38.44 or 39.71 in combination with diagnosis code of 441.4. This analysis also used MS-DRGs 237 and 238 because both procedure codes map to these MS-DRGs. The applicant found 2,981 cases (or 13.6 percent of all cases) in MS-DRG 237 and 18,928 cases (or 86.4 percent of all cases) in MS-DRG 238. The applicant removed those cases that had both procedure codes 38.44 and 39.71 on the claim. The case-weighted average charge per case was $80,948. Using the same methodology described above, the applicant determined a final case-weighted average standardized charge per case of $86,081. Using the FY 2013 Table 10 thresholds, the case-weighted threshold for MS-DRGs 247 and 238 was approximately $73,964. As above, because the FY 2013 Table 10 thresholds for MS-DRGs 237 and 238 are higher than the thresholds for MS-DRGs 252, 253, and 254, the applicant believes the Zenith® F. Graft meets the cost criterion when compared with MS-DRGs that are mapped to the device.

CMS invites public comment on whether on not the Zenith® F. Graft meets the cost criterion for new technology add-on payments. CMS appreciates the multiple analyses of the FY 2010 MedPAR data but expresses concerns that the second and third analyses with this data did not remove charges for other services such as extra operating room time and other possible charges that would be incurred during an open procedure, but would possibly not be incurred during cases when the Zenith® F. Graft is implanted. CMS also invites comments on the methodology used, specifically whether and the degree to which the second and third analyses may contain charges not relevant to the final case-weighted standardized charge per case determined by the applicant.

Substantial Clinical Improvement Criterion,
The applicant states that Zenith® F. Graft meets the substantial clinical improvement criterion. The applicant notes that 30 to 40 percent of patients who have an infrarenal AAA cannot be treated with current commercial devices because of anatomical reasons. The applicant also states that the Zenith® F. Graft offers an additional AAA repair option to patients who have limited surgical treatment options (for example, if short infrarenal neck lengths make a patient too high a risk to be a candidate for an open surgical repair). Several sources of literature are referenced to support the use of the Zenith® F. Graft as a less invasive treatment option than open surgical repair including reduced peri-operative mortality, reduced morbidity by reducing renal failure requiring permanent dialysis, shorter hospital stay and less operative blood loss for the

fenestrated endovascular aortic repair as compared to the open repair of juxtarenal AAA.

CMS is concerned that although the applicant compared this technology to open surgical repair they did not present publicly available information comparing this technology to medical management, which the applicant mentions as another method for treating patients that are anatomically unsuited for currently approved AAA endovascular grafts. CMS is also concerned that information regarding the longevity of the Zenith® F. Graft as well as long-term complications and secondary interventions or reinterventions has not been presented. CMS also notes that they are concerned that the clinical study data presented was nonrandomized, did not differentiate between patients by infrarenal neck length and/or suitability for other endovascular grafts, and were of noninferiority.

CMS invites comments on whether or not the Zenith® F. Graft meets the substantial clinical improvement criterion.

III. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

A. Reports on the Medicare Wage Index

On April 11, 2012, the Secretary submitted to Congress a report to reform the Medicare Wage Index using the concept of a Commuting Based Wage Index (CBWI) to replace the current Medicare wage index methodology. The CBWI would use commuting data of hospital employees commuting from home to work to define hospital labor market areas thereby aggregating wage data based on worker residence rather than a CBSA-based area where a hospital is located. A CBWI methodology would use commuting flows to identify specific areas, with a potential specificity of zip codes or rural census tracts, to determine the proportion of hospital employees hired from each area, using either hospital cost report data or, perhaps, Bureau of Labor Statistics (BLS) Occupational Employment Survey data. A hospital's benchmark wage level would be calculated as the weighted average of hiring proportions by area and area wage levels and then divided by the national average.

The Secretary believes that a CBWI methodology "would yield wage index values that more closely correlate to actual labor costs than either the current wage index system (with or without geographic reclassification) or a system that attempts to reduce wage index differences across geographic boundaries, such as MedPAC's proposed wage index based on [BLS] data for health care industry workers"; further, while the CBWI methodology would permit variation within a CBSA, those variations would likely be less severe and less likely to result in large differences (i.e., cliffs) among hospitals within adjacent CBSAs. However, stakeholders expressed concerns in an April 12, 2011, open door forum over the availability of commuting data, continuation of certain current law exceptions and adjustment policies, and the impacts of the CBWI upon other nonhospital payment systems; concerns were also raised that a CBWI may encourage providers to manipulate hiring practices in order to improve wage index

calculations. While CMS is not convinced that providers will alter hiring practices, the agency agrees that a CBWI may not be appropriate or even calculable for non-hospital payment systems.

The Secretary commissioned the Institute of Medicine (IOM) to recommend changes to the wage index. IOM recommends changing the "current labor market definitions to account for the out-commuting patterns of health care workers who travel to a place of employment in an MSA other than the one in which they live". IOM recommends assigning each hospital within a county in an MSA the county area wage index determined by 1) first computing a wage index for each MSA using the current methodology (before hospital reclassification); and 2) computing an area wage for each county within the MSA equal to the weighted average of MSA-level average hourly wages (using the BLS Occupational Employment Survey) for all health care workers, where the weight for each MSA would measure the share of all hospital workers living in the county who commute to hospitals located in that MSA. The wage indices would then be normalized for budget neutrality.

While the IOM recommendations would reduce the cliffs among wage levels in adjacent areas, the Secretary is concerned about the limitation of the average hourly wage computation to only those health care workers who live near a hospital versus those who could be employed there. The Secretary also reflects concerns expressed by hospitals and hospital associations on the operational and other challenges of using the BLS Occupational Employment Survey. The proposed rule includes a chart that compares the key features of the various recommendations to revise the wage index methodology.

B. Core-Based Statistical Areas for the Hospital Wage Index

CMS proposes to use the same labor market areas in FY 2013 that it used for the FY 2012 wage index because OMB will not announce before CY 2013 new area delineations based on the OMB 2010 standards and 2010 census data.

C. Worksheet S-3 Wage Data

CMS notes that the proposed wage index values are based on data from FY 2009 submitted cost reports, and include categories of costs paid under the IPPS (and outpatient costs) for salaries and hours from short term, acute care hospitals, home office costs and hours, contract labor costs and hours (including direct and certain indirect patient care, pharmacy, lab, and nonteaching physician Part A services), and wage related costs (including pension costs). Excluded categories of costs are direct and overhead salaries and hours for services not subject to IPPS payment (e.g., SNF and home health services), hospital-based RHCs and FQHCs, and CAHs. CMS also notes this data is used to calculate wage indices for other providers of services as well as for prospective payments to IRFs, IPFs, and LTCHs.

CMS calculates the proposed FY 2013 wage index based on data from 3,443 hospitals. In reviewing submitted data from Worksheet S-3, CMS excludes 32 providers due to excessively aberrant data but indicates that, if the data could be corrected in time, it intends to include some of those providers in the final wage index for FY 2013. CMS includes data from IPPS hospitals in 2009 even if they terminated program participation as hospitals, but excludes data from CAHs and IPPS hospitals that converted to CAH status. For a multicampus hospital, CMS uses the same methodology as it did for the FY 2012 wage index to allot wages and hours data among the different labor market areas where the campuses are located. Table 2, available from the CMS Web site, includes separate wage data for multicampus hospitals.

D. Method to Compute Proposed FY 2013 Unadjusted Wage Index

The proposed national average hourly wage, unadjusted for occupational mix, is $37.4023 ($15.8467 for Puerto Rico). CMS uses the same methodology it applied for the FY 2012 wage index in computing the unadjusted wage index for FY 2013. CMS notes that it does not propose to change the use of the employment cost index as its data source for wages, salaries and other price proxies in the IPPS market basket.

E. Occupational Mix Adjustment for the FY 2012 Wage Index

The proposed FY 2013 occupational mix-adjusted national average hourly wage is $37.3721; the FY 2013 proposed occupational mix-adjusted Puerto Rico-specific average hourly wage is $15.8838.

The Act provides for the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program in order to construct an occupational mix adjustment to the wage index. The FY 2013 hospital wage index is based on data collected on the new 2010 Medicare Wage Index Occupational Mix Survey. For FY 2013, CMS proposes to use the same methodology it used for FY 2012.

As it did for FY 2012, CMS applies the occupational mix adjustment to 100 percent of the FY 2013 wage index. The proposed FY 2013 national average hourly wages for each occupational mix nursing subcategory are as follows:

Occupational Mix Nursing Subcategory	Average Hourly Wage
National RN	$37.362735568
National LPN and Surgical Technician	$21.762566488
National Nurse Aide, Orderly, and Attendant	$15.312800678
National Medical Assistant	$17.240367808
National Nurse Category	$31.807020884

The proposed wage index values for FY 2013 are included in Tables 4A, 4B, 4C, and 4F of the Addendum to the proposed rule, and include the proposed national rural and imputed floor budget neutrality adjustment as well as the proposed outmigration adjustment for eligible hospitals.

CMS observes that, based on its analysis of the occupational mix data, the national percentage of hospital employees in the nurse category is approximately 43 percent, and that the proposed wage index values for FY 2013 would increase for two-thirds of rural areas and for slightly more than half of urban areas.

Proposed Rural, Imputed, and Frontier Floors

CMS notes that the rural floor will increase the FY 2013 proposed wage index for 393 hospitals. CMS projects that, in aggregate, rural hospitals will experience a -0.3 percent decrease in payments as a result of the rural floor budget neutrality requirement; hospitals located in other urban areas (populations of 1 million or fewer) will experience a 0.1 percent increase in payments; and urban hospitals in the New England region can expect a 3.1 percent increase in payments primarily, due to the application of the rural floor in Massachusetts. CMS expects that all 60 urban providers in Massachusetts will receive a rural floor wage index value, including rural floor budget neutrality, of 1.3047 and will receive approximately a 5.5 percent increase in IPPS payments due to the application of rural floor.

For States that lack a rural hospital to set a wage index (i.e., New Jersey and Rhode Island), CMS previously established a temporary program under regulations whereby CMS imputes a "floor" for these all-urban States but which in practice only benefits New Jersey. Though the temporary program will expire at the end of FY 2013, CMS proposes an alternative, temporary methodology for the benefit of Rhode Island, which has only one CBSA in contrast to New Jersey's 10. Under this alternative, the lowest post-reclassified wage index assigned to a hospital in a State with one CBSA (viz. Rhode Island) would be increased by a factor equal to the average percentage difference between the post-reclassified, pre-floor area wage index and the post-reclassified, rural floor wage index (absent rural floor budget neutrality). Four hospitals in Rhode Island would benefit from the alternative temporary methodology; CMS estimates an additional $4.8 million in payments in FY 2013. Twenty-nine hospitals in New Jersey would benefit from the previously established temporary methodology; CMS estimates an aggregate increase in payments of roughly $18 million in FY 2013.

Montana, North Dakota, South Dakota, and Wyoming would receive the frontier floor value of 1.0000; though Nevada qualifies as a frontier State, its proposed rural floor value (1.0293) is greater than the frontier floor. Overall, CMS estimates an approximately $53 million increase in IPPS operating payments in FY 2013 by reason of the frontier floor.

F. Revisions to the Wage Index Based on Hospital Redesignations and Reclassifications

CMS notes that 238 hospitals were approved for wage index reclassifications for FY 2013 by the Medicare Geographic Classification Review Board (MGCRB), and, because such reclassifications are effective for 3 years, a total of 770 hospitals are in a reclassification status for FY 2013 (including those initially approved by the MGCRB for FY 2011 and FY 2012). Applications for FY 2014 reclassifications are due to the MGCRB by September 4, 2012 which is also the deadline for canceling a previous wage index reclassification withdrawal or termination. Changes to the wage index by reason of reclassification withdrawals, terminations, wage index corrections, appeals and the CMS review process would be incorporated in the final FY 2013 wage index values.

CMS reminds readers that a "Lugar" hospital may apply to the MGCRB to reclassify to a different area and may compare the impact of any such reclassification in Table 4C of the proposed rule. The hospital would have 45 days from the date of publication of the proposed rule to withdraw from an MGCRB reclassification. Further, an eligible hospital that waives its Lugar status to receive the out-migration adjustment is treated as rural for all purposes (including for the rural DSH adjustment) for each fiscal year for which it receives the out-migration adjustment. CMS permits a Lugar hospital to submit a single notice to automatically waive its deemed urban status for the 3-year period of the out-migration adjustment, though the hospital is permitted before its second or third year of eligibility to notify CMS to return to its deemed urban status.

CMS notes that the latest extension of the section 508 hospital reclassifications, under section 3001 of the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112-96), expired at the end of March 2012, and thus will not be applicable for purposes of FY 2013. CMS estimates that payments will decrease by 0.1 percent.

G. FY 2013 Wage Index Adjustment Based on Commuting Patterns of Hospital Employees

Table 4J (available from the CMS Web site) lists the proposed out-migration wage index adjustments for FY 2013. CMS proposes to use the same policies, procedures and computation that were used for the FY 2012 out-migration adjustment. It estimates increased payments of approximately $18 million for providers receiving the out-migration adjustment.

H. Process for Requests for Wage Index Data Correction

CMS describes the process (see table below) by which a hospital may submit to its fiscal intermediary or Medicare Administrative Contractor (FI/MAC) requests to change or revise wage index data, and indicates that June 4, 2012 is a hospital's last opportunity to request a correction to an error the hospital determines was made after review of the CMS final wage index data public use files which will be made available

in early May 2012. CMS further indicates that it would only make a change to wage and occupational mix data under very limited circumstances, namely that 1) the error was made by the FI/MAC or CMS; and 2) the hospital could not have known about the error before its review of the final wage index data files. A hospital that can meet these two requirements must send a letter to both its FI/MAC and CMS explaining the error and providing full documentation to support its claim, including when it became aware of the error.

Date/Deadline	Wage Index Data Related Action
October 4, 2011	Preliminary unaudited wage data and occupational mix survey data available on CMS Web site
December 5, 2011	Deadline to submit corrections with detailed explanation to FI/MAC for desk review
Mid-February 2012	FI/MAC notifies hospitals of any changes due to desk review and submits revised data to CMS
February 21, 2012	CMS publishes proposed wage index public use files, including hospital revised wage index data
March 5, 2012	Deadline to submit to FI/MAC request for reconsideration of adjustment made by FI/MAC due to desk review
April 11, 2012	Deadline for FI/MAC to transmit additional revisions due to hospital reconsideration request
April 18, 2012	Deadline for hospital to seek CMS intervention where hospital disagrees with FI/MAC policy interpretation
Early May, 2012	CMS to release final wage index data public use files: only purpose for review is to identify potential CMS or FI/MAC errors in the entry of final wage index data from the correction process (e.g., revisions submitted to CMS by FI/MACs by April 11, 2012)
June 4, 2012	Deadline for receipt of hospital letters to FI/MAC and CMS describing and explaining erroneous wage or occupational mix data (with supporting information)

CMS provides examples of the types of requests that will not be approved: for example, data corrections submitted too late for the April 11, 2012 transmission; review of fact determinations or policy interpretations by FI/MACs during the wage index correction process.

Verified corrections that are timely received by CMS would be incorporated in the final wage index and be effective October 1, 2012. Hospitals that do not meet the procedural timelines would not be able to appeal any CMS failure to make the requested data revision to the PRRB. However, CMS does reserve the right (not the obligation) to make mid-year corrections to errors that hospitals bring to their attention after the June 4, 2012 deadline under limited circumstances as follows: 1) the FI/MAC or CMS erred in tabulating its data; and 2) the hospital could not have known about the error, or could not have had an opportunity to correct the error, by the June 4 deadline. If such a correction would change the wage index value for an area, the revised wage index would be effective prospectively from the correction date.

Only under very limited circumstances would CMS make wage index value changes retroactive to the beginning of the fiscal year involved, as follows: 1) the FI/MAC or CMS erred in tabulating data; 2) the hospital knew and requested a correction before June 4; and 3) CMS agreed that the error was made and should be corrected. However, this would not apply for a hospital that seeks to revise another hospital's data; nor can the correction be used to revise a prior fiscal year's wage index data. CMS notes that there would also be retroactive effect where a judicial decision reverses a CMS denial of a hospital's wage index revision request.

I. Labor-Related Share for the FY 2013 Wage Index

CMS proposes to continue to use a labor-related share of 68.8 percent for discharges occurring on or after October 1, 2012. This is the same labor-related share used in FY 2012. Tables 1A and 1B in section VI. of the Addendum to the proposed rule reflect this labor-related share. CMS proposes to apply the wage index to the labor related-share of 62 percent of the national standardized amount for hospitals with wage indices less than 1.0000 and 68.8 percent of the national standardized amount for hospitals with wage indices greater than 1.0000. CMS does not propose any further changes to the national average proportion of operating costs attributable to wages and salaries, fringe benefits, contract labor, other labor-related services, etc.

For Puerto Rico hospitals, CMS proposes to continue to use a labor-related share for the Puerto Rico-specific standardized amounts of 62.1 percent for discharges occurring on or after October 1, 2012; the labor-related share of a hospital's Puerto Rico-specific rate will be either the Puerto Rico-specific labor-related share of 62.1 percent or 62 percent, whichever results in higher payments to the hospital.

IV. Other Proposed Decisions and Changes to the IPPS for Operating Costs and GME Costs

A. Hospital Readmissions Reduction Program

Effective October 1, 2012, section 3025 of the ACA reduces payments to Medicare PPS hospitals with readmissions exceeding an expected level. The payment reductions are based on a formula that compares each hospital’s payments for actual readmissions (risk-adjusted) to payments based on an estimate of that hospital’s expected readmissions (also risk-adjusted). In the FY 2012 final rule, CMS identified three conditions, Acute Myocardial Infarction (AMI), Heart Failure (HF) and Pneumonia (PN) to be used for the Hospital Readmissions Reduction Program.

CMS chose to implement the readmissions reduction program over 2 years. The FY 2012 IPPS final rule addressed:

(i) Aspects of the program relating to the conditions and readmissions to which the program will apply for the initial year beginning October 1, 2012;
(ii) The readmission measures and related methodology used for those measures, as well as the calculation of the readmission rates; and
(iii) Public reporting of the readmission data.

The FY 2013 proposed IPPS rule establishes proposed policies related to the payment adjustment and other issues:

(i) Base operating DRG payment amounts, including policies for SCHs and MDHs;
(ii) Adjustment factor (both the ratio and the floor adjustment factor);
(iii) Aggregate payments for excess readmissions and aggregate payments for all discharges;
(iv) Applicable hospital;
(v) Limitations on review; and
(vi) Reporting of hospital-specific information, including the process for hospitals to review and submit corrections.

In future years' rulemaking, CMS plans to expand the list of applicable conditions beyond the initial 3 conditions and add 4 conditions that have been identified by MedPAC for the Program.

Provisions finalized in FY 2012 IPPS rule. The FY 2013 proposed rule summarizes the provisions of the Readmissions Reduction Program that CMS finalized in the FY 2012 IPPS rule, as follows.

Applicable Conditions for FY 2013: CMS determined heart failure (HF), acute myocardial infarction (AMI), and pneumonia (PN) meet the statutory requirement (section 1886(q)(5)(A)) that the "applicable conditions" be conditions or procedures for which readmissions are "high volume or high expenditure" and for which "measures of such readmissions" have been endorsed by the National Quality Forum (NQF). CMS also determined that they have "exclusions for readmissions that are unrelated to the prior discharge," as required by the law.

Definition of "Readmission". A readmission is an admission to an acute care hospital within a time period of 30 days from the date of discharge from the index hospital to a non-acute setting (for example, home health, skilled nursing, rehabilitation or home) as specified in the existing NQF-endorsed measures. If there are multiple readmissions within the 30 days, only one will count in calculating the readmission ratios.

Readmission Measures and Related Methodology

1. Readmission Measures

CMS adopted these NQF-endorsed, risk-standardized readmission measures which are currently in the hospital IQR program:

- Acute Myocardial Infarction 30-day Risk Standardized Readmission Measure (NQF#0505)
- Heart Failure 30-day Risk Standardized Readmission Measure (NQF#0330)
- Pneumonia 30-day Risk Standardized Readmission Measure (NQF#0506)

2. NQF Endorsement of Measures of Readmissions

CMS adopted the measures and related methodologies as they are currently endorsed by NQF, concerned that if it modifies the endorsed measures, they would no longer be

considered "endorsed". If NQF were to later endorse a revised measure for one of these conditions, CMS would propose through notice and comment rulemaking that the revised measure be used prospectively for the Program.

3. Endorsed Measures with Exclusions for Unrelated Readmissions

CMS adopted, without revision or modification, the exclusions for unrelated admissions set forth in the existing NQF-endorsed measures.

- AMI readmission measure. The measure does not count admissions after discharge that include PTCA or CABG procedures as readmissions, unless the principal discharge diagnosis for the readmission is heart failure, acute myocardial infarction, unstable angina or cardiac arrest.
- HF and PN readmission measure. There are no exclusions for these measures of readmissions because during the development of the IQR measures, clinical experts did not identify planned procedures as occurring commonly after admissions for HF or PN.

Transfers to other acute care facilities will be excluded from each of the readmission measures. Thus, in the case of a patient who is transferred between two or more hospitals, if the patient is readmitted in the 30 days following the final hospitalization, the measures attribute the readmission to the hospital that discharged the patient to a non-acute care setting.

4. Measurement methodology

Additional details about each of these measures may be found online at QualityNet at: http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069855841

The measures are risk-standardized rates of readmission and include the following steps:

- For each hospital, qualifying index hospitalizations are identified based on the principal discharge diagnosis of the patient and the inclusion/exclusion criteria (see Index Hospitalization below).
- Each hospitalization is evaluated for whether the patient had a readmission to an acute care setting in the 30 days following discharge (as defined above). Patient-risk factors, including age and chronic medical conditions, are also identified from inpatient and outpatient claims for the 12-months prior to the hospitalization for risk adjustment (see risk adjustment below).
- The readmissions, sample size for each hospital, and patient risk-factors are then used to calculate a risk-standardized readmission ratio for each hospital.
- For public-reporting of these measures, this risk-standardized readmission ratio is multiplied by the national crude rate of readmission for the given condition to produce a risk-standardized readmission rate (RSRR).

Index Hospitalization: An index hospitalization for each of the readmission measures is the hospitalization from which CMS evaluates the 30 days after discharge for possible readmissions. The NQF-endorsed measures exclude patients under 65 year of age. The discharge diagnoses for each measure are based on a list of specific ICD-9-CM codes for that condition, which are posted on the QualityNet.org website. The currently applicable

ICD-9-CM diagnosis codes are listed in the FY 2013 proposed rule (pp. 357-359 of display copy).

The following admissions are excluded from the group of index hospitalizations:

- Hospitalizations for patients with an in-hospital death
- Hospitalizations for patients without at least 30 days post-discharge enrollment in fee-for-service Medicare (FFS)
- Hospitalizations for patients discharged against medical advice

Readmission. Except for exclusions noted above, a patient who is readmitted twice within 30 days is counted simply as having been readmitted; this patient's readmissions are not counted differently than a patient with a single readmission within 30 days of discharge. All readmissions are included, without regard to the principal diagnosis of readmission.

Time Window. Readmissions are counted within a 30-day period from the date of the initial discharge from the index hospitalization.

Risk Adjustment. To calculate the RSRRs, CMS adopted a methodology that adjusts for key factors that are clinically relevant and have strong relationships with the outcome (for example, patient demographic factors, patient co-existing medical conditions, and indicators of patient frailty). Under the current NQF-endorsed methodology, these covariates are obtained from Medicare Part A and Part B claims extending 12 months prior to, and including, the index admission. This risk-adjustment approach adjusts for differences in the clinical status of the patient at the time of the index admission as well as for demographic variables.

The risk adjustment variables for each condition are presented on the QualityNet.org website in the 2010 Measures Maintenance Technical Report: Acute Myocardial Infarction, Heart Failure, and Pneumonia 30-Day Risk-Standardized Readmissions Measures. The variables used are Condition Categories that group ICD-9-CM codes into clinically coherent variables. The 2010 Condition Category-ICD-9-CM Crosswalk provides a map to the specific ICD-9-CM codes in each variable. A complete list of the variables used for risk adjustment and the clinical and statistical process for selecting the variables for each NQF-endorsed measure is available in the publicly-available technical documentation of the existing readmission measures for AMI, HF, and pneumonia.

Applicable Period. For the FY 2013 Hospital Readmissions Reduction Program, three years of discharge data, from July 1, 2008 through June 30, 2011, are used as the applicable period to calculate excess readmission ratios for each of the three proposed measures. The modeling and impact analysis for the proposed rule uses an earlier 3-year period, July 1, 2007 through June 30, 2010.

Data Sources. For risk adjustment analysis, CMS uses Medicare administrative claims datasets that contain FFS inpatient and outpatient claims information (Medicare Parts A and B) in the prior 12 months and subsequent one month for patients. If the patient does

not have any claims in the 12 months prior to the index hospitalization admission, only co-morbidities from the included admission are used.

Minimum Number for Applicable Conditions. Based on the experience with the IQR program, CMS uses the threshold of 25 discharges for each of the three measures for the program.

Reporting Hospital-Specific Readmission Rates. CMS uses a similar process and timeframe for rates calculated for the Hospital Readmissions Reduction Program as is currently used for the reporting of the three readmission rates on the *Hospital Compare* website. Hospitals are provided the opportunity to preview their readmission rates for 30 days and submit comments to CMS before posting.

5. *Excess Readmission Ratio.* CMS uses the risk-standardized ratio calculated for AMI, HF, and PN as the "excess readmission ratio". This is defined as a ratio of the number of risk-adjusted readmissions (based on actual readmissions) for the given condition at a specific hospital compared with the number of readmissions that would be expected for an average hospital caring for the same patients. This ratio is used as part of the Hospital IQR Program.

The ratio is a measure of relative performance. If a hospital performs better than an average hospital that admitted similar patients (same risk factors for readmission), the ratio will be less than one. If a hospital performs worse than average, the ratio will be greater than one. Hospitals with a ratio greater than one have excess readmissions relative to average quality hospitals with similar types of patients.

Numerator and Denominator of the Risk-standardized Ratio (Excess Readmission Ratio). The risk-standardized ratio is calculated using hierarchical logistic modeling, which CMS identifies as a widely accepted statistical model that evaluates relative hospital performance based on outcomes such as readmission. The statistical model analyzes data on all the patients discharged from all hospitals for a given condition which indicate what co-morbidities were present when the patient was admitted and whether or not the patient was readmitted.

The model estimates the amount by which a specific hospital increases or decreases patients' risk of readmission relative to an average hospital based on the hospital's actual readmissions relative to other hospitals with similar patients. The estimated amount each hospital contributes (or subtracts) from its patients' readmission risk compared to hospitals with similar patients is called the "hospital-specific readmission effect". It is used only in the numerator to estimate the adjusted actual readmissions. The denominator reflects national average readmissions for a similar set of patients.

The ratio compares the total adjusted actual readmissions at the hospital to the number that would be expected if the hospital's patients were treated at an average hospital with similar patients. Hospitals with more adjusted actual readmissions than expected

readmissions will have a risk-standardized ratio (excess readmission ratio) greater that one.

Provisions in the FY 2013 Proposed Rule. The readmissions provision specifies that for each relevant clinical condition (such as heart failure), the payment formula determines the "excess readmission ratio," as defined above. Next, the formula calculates the amount of aggregate payments due to excess readmissions for each condition by multiplying the total number of admissions for the condition times the average base operating DRG payment for the condition times the excess readmission ratio for the condition. Under the Hospital Readmissions Reduction Program, payments for discharges from an "applicable hospital" will be an amount equal to the product of the "base operating DRG payment amount" and an "adjustment factor" based on the aggregate payments for excess readmissions. CMS proposes regulatory definitions of several terms largely repeating the statutory definitions.

Base operating DRG payment amount is the DRG payment for operating costs excluding adjustments for VBP, IME, DSH, low-volume hospitals, and outliers. It includes new technology payments and is wage-adjusted, including COLA adjustments for Alaska and Hawaii. For SCHs that receive payments based on their hospital-specific payment rate, the base operating DRG payment amount excludes the difference between the hospital's applicable hospital-specific payment rate and the Federal payment rate. (A similar policy applies to MDHs prior to the scheduled termination of that program effective October 1, 2012.) The proposed definition of "base operating DRG payment amount" would be used to calculate both the "aggregate payments for excess readmissions" and "aggregate payments for all discharges," which would then be used to determine the readmission adjustment factor as well as the payment amounts to be adjusted for excess readmissions. CMS proposes to use MedPAR claims data to determine the base operating DRG payment amounts; it will use the update of the MedPAR file that is updated 6 months after the end of each federal fiscal year (that is, the March updates of the respective federal fiscal year MedPAR files). These are the same MedPAR files that are used in the annual IPPS rulemaking.

The readmissions adjustment factor is defined as equal to the greater of: (i) 1 minus the ratio of the aggregate payments for excess readmissions to aggregate payments for all discharges or (ii) the floor adjustment factor. The statute specifies that the floor adjustment factor is 0.99 for FY 2013, 0.98 for FY 2014, and 0.97 for FY 2015 and subsequent fiscal years. The floor adjustment factor limits the payment reduction applicable to the base operating DRG payments to 1 percent in FY 2013, 2 percent in FY 2014, and 3 percent in FY 2015 and subsequent years. The proposed rule establishes these payment formulas:

Aggregate payments for excess readmissions = [sum of base operating DRG payments for AMI x (Excess Readmission Ratio for AMI-1)] + [sum of base operating DRG payments for HF x (Excess Readmission Ratio for HF-1)] + [sum of base operating DRG payments for PN x (Excess Readmission Ratio for PN-1)].

Aggregate payments for all discharges = sum of base operating DRG payments for all discharges.

Ratio = 1-(Aggregate payments for excess readmissions/Aggregate payments for all discharges).

Readmissions Adjustment Factor for FY 2013 is the higher of the ratio or 0.99.

CMS proposes to define applicable hospital to include both (1) subsection (d) hospitals, that is, hospitals paid under the IPPS and (2) hospitals in Maryland that are paid under section 1814(b)(3) of the Act and that, absent the waiver specified by section 1814(b)(3) of the Act, would have been paid under the IPPS. These hospitals are not applicable hospitals: CAHs; Puerto Rico hospitals or hospitals in the Territories; and hospitals and hospital units excluded from the IPPS, such as LTCHs, cancer hospitals, children's hospitals, IRFs, and IPFs. An Indian Health Service hospital enrolled as a Medicare provider is an applicable hospital. The statute defines "readmission" as "in the case of an individual who is discharged from an applicable hospital, the admission of the individual to the same or another applicable hospital within a time period specified by the Secretary from the date of such discharge." Excess readmission ratios calculated for the purpose of the Hospital Readmissions Reduction Program would include only admissions and readmissions to "applicable hospitals." These excess readmission ratios will differ from the readmission rates reported on Hospital Compare for the purpose of the Hospital IQR Program since excess readmission ratios for the purpose of the Hospital IQR Program were determined based on admissions and readmissions to all hospitals.

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Impact on DSH hospitals. Many commenters during the FY 2012 IPPS rulemaking cycle expressed concern that hospitals treating a high proportion of low-income patients may have higher readmission rates and could be unfairly penalized under the Hospital Readmissions Reduction Program. The proposed rule includes a table showing the estimated distribution of the readmission adjustment factors among hospitals ranked by their DSH patient percentage (DPP). CMS makes no proposal or conclusions based on the table, but invites public comment.

DISTRIBUTION OF HOSPITALS READMISSION ADJUSTMENT FACTOR BY DSH PATIENT PERCENTAGE (DPP)

Decile	Number of Hospitals	Payment Adjustment of less than -1 percent	-1 Percent Floor Adjustment	No Readmission Adjustment Factor
Lowest DPP	339	156	38	145
Second	339	164	57	118
Third	339	168	44	127
Fourth	339	170	48	121
Fifth	339	182	42	115
Sixth	339	171	43	125
Seventh	339	187	44	108

Decile	Number of Hospitals	Payment Adjustment of less than -1 percent	-1 Percent Floor Adjustment	No Readmission Adjustment Factor
Eighth	339	182	43	114
Ninth	339	179	58	102
Highest DPP	342	185	61	96
Total	3,393	1,744	478	1,171

The proposed rule also includes a table showing the distribution of proposed readmission adjustment factors modeled using 2007-2010 data (rather than the 2008-2011 that will be used for the final rule adjustments. The table shows that about 71 percent of hospitals would receive either no adjustment or a readmission adjustment factor that would reduce their base operating DRG payments by less than 0.5 percent.

DISTRIBUTION OF READMISSION ADJUSTMENT FACTORS

Percent Reduction	Number of Hospitals	Percent of Hospitals
No Adjustment	1,171	34.5%
Up to -.09 Percent	347	10.2%
-0.1 Percent to -0.19 Percent	280	8.3%
-0.20 Percent to -0.29 Percent	228	6.7%
-0.30 Percent to -0.39 Percent	196	5.8%
-0.40 Percent to -0.49 Percent	180	5.3%
-0.50 Percent to -0.59 Percent	129	3.8%
-0.60 Percent to -0.69 Percent	118	3.5%
-0.70 Percent to -0.79 Percent	110	3.2%
-0.80 Percent to -0.89 Percent	77	2.3%
-0.90 Percent to -0.99 Percent	76	2.2%
-1.0 Percent	481	14.2%
Total	3,393	100.0%

Reporting Hospital-Specific Information, Including Opportunity to Review and Submit Corrections. For FY 2013, CMS proposes to deliver confidential reports and accompanying confidential discharge-level information to applicable hospitals containing their excess readmission ratios for the three applicable conditions. The reports will be delivered in hospitals' secure QualityNet accounts by June 20, 2012. Hospitals will have 30 days to review the report and submit corrections. The discharge-level information accompanying the excess readmission ratios would include the risk-factors for the discharges that factor into the calculation of the excess readmission ratio, as well as information about the readmissions associated with these discharges (such as dates, provider numbers, and diagnosis upon readmission). CMS will incorporate appropriate corrections to the excess readmission ratio calculations prior to the publication of the final rule, when the excess readmission ratios would

be made available to the public in a table to be cited in the final rule and available via the Internet on the CMS Web site.

The proposed rule would not allow hospitals to submit corrections related to the underlying claims data used to calculate the ratios, or allow hospitals to add new claims to the data extract used to calculate the ratios. CMS proposes to create data extracts using claims in the Common Working File (CWF) 90 days after the last discharge date in the applicable period which is used for the calculations. For example, if the last discharge date in the applicable period for a measure is June 30, 2011, CMS would create the data extract on September 30, 2011, and use that data to calculate the ratios for that applicable period. Hospitals would not be able to submit corrections to the underlying data that were extracted on September 30, 2011, and would also not be able to add claims to the data set.

PPS Waiver Hospitals Paid under Section 1814(b)(3) of the Act. The statute allows the Secretary to exempt Maryland waiver hospitals from the Hospital Readmissions Reduction Program, provided that the State submits an annual report to the Secretary describing how a similar program to reduce hospital readmissions in that State achieves or surpasses the measured results in terms of health outcomes and cost savings. The proposed rule provides that (1) CMS will establish criteria for evaluation of Maryland's annual report to the Secretary to determine whether Maryland will be exempted from the program for a given fiscal year and (2) Maryland's annual report to the Secretary and request for exemption from the Hospital Readmissions Reduction Program must be resubmitted and reconsidered annually.

Limitations on Review. The statute provides that there will be no administrative or judicial review under section 1869 of the Act, under section 1878 of the Act, or otherwise for the determination of base operating DRG payment amounts or the methodology for determining the adjustment factor, including the excess readmissions ratio, aggregate payments for excess readmissions, and aggregate payments for all discharges, and applicable periods and applicable conditions.

B. Sole Community Hospitals (SCHs)

Generally, classification of a hospital as an SCH remains in effect unless a change specified in regulations (clauses (A) through (E) of § 412.92(b)(3)(ii)) occurs or unless the hospital becomes aware of a change that would affect its status. Failure to report a change will result in retroactive loss of SCH status to the date of the change or the hospital's awareness of the change, subject to reopening rules. CMS notes that its regulations do not address circumstances where a hospital that never met the criteria was nonetheless granted SCH status, and CMS proposes to clarify what it describes as its current authority to make the withdrawal of SCH status for such a hospital retroactive for the entire time period of its SCH classification, again subject to reopening rules. CMS further believes that a hospital with SCH status is under an obligation to report not just changes that may affect SCH status but also any relevant factor or other information. CMS does not believe there will be any significant impact of the proposal because it would only affect hospitals incorrectly classified as SCHs.

CMS notes that the current Medicare-dependent, small rural hospital (MDH) program will, under current law, expire on September 30, 2012, and seeks to provide a seamless transition for an MDH hospital that seeks to apply for SCH classification effective October 1, 2012. CMS proposes that the MDH hospital would have to apply by September 1, 2012, and specifically request an effective date for the SCH classification concurrent with the expiration of the MDH program. If approved, CMS proposes an effective date of October 1, 2012, for the SCH classification. CMS declines to quantify any payment impact for this proposal due to lack of any data from hospitals regarding their intentions to utilize this proposal.

C. Rural Referral Centers

CMS proposes revised criteria for purposes of determining rural referral center (RRC) status, including updated minimum national and regional case mix index (CMI) values and updated minimum national and regional numbers of discharges. These factors are among those used to determine whether a given hospital qualifies for RRC status.

More specifically, to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2012, CMS proposes that a rural hospital with fewer than 275 beds available for use must, among other things:

- Have a CMI value for FY 2011 that is at least 1.5378 or the newly updated median CMI value (not transfer adjusted) for urban hospitals (excluding hospitals with approved teaching programs) calculated by CMS for the census region in which the hospital is located. These proposed median regional CMIs are listed in the proposed rule and will be revised in the final rule to the extent necessary to reflect the updated FY 2011 MedPAR file.
- Have as the number of discharges for its applicable cost reporting period (described below) a figure that is at least 5,000 (3,000 for an osteopathic hospital) or the newly updated median number of discharges for urban hospitals in the census region in which the hospital is located. However, since the proposed median number of discharges for hospitals in each census region is greater than the national standard of 5,000 discharges, CMS notes that 5,000 discharges is the minimum criterion for all hospitals (3,000 for osteopathic hospitals).

Due to a transition in the CMS cost reporting system for cost reporting periods beginning on or after May 1, 2010, CMS reports using FY 2009 cost report data for those providers with fiscal years beginning during the 5-month period beginning on May 1, 2010, in addition to FY 2010 cost report data for providers with fiscal years beginning during the October 1, 2009 through April 30, 2010 period.

D. Payment Adjustment for Low-Volume Hospitals

The ACA-revised criteria for the low-volume payment adjustment expires at the end of FY 2012; thus, for discharges occurring during FY 2013, the criteria for this adjustment reverts back to those in effect before FY 2011: the road mileage qualifying criterion reverts to 25 road miles from the nearest subsection (d) hospital and the discharge

qualifying criterion reverts to no more than 200 total (Medicare and non-Medicare) discharges. A hospital seeking this adjustment must provide sufficient documentation to its FI/MAC that it meets the discharge and distance requirements by not later than September 1, 2012, for the adjustment to apply to discharges made on or after the beginning of FY 2013. CMS indicates that a Web-based mapping tool may be used for the mileage criterion. For requests submitted after September 1, 2012 that are approved, the adjustment will apply prospectively to discharges beginning on or after the date that is 30 days after the FI/MAC approval date.

CMS estimates approximately 600 hospitals that qualified as a low-volume hospital for FY 2012 will no longer meet the mileage and discharges criteria to qualify in FY 2013, resulting in
projected reduction in payments of roughly $300 million in FY 2013 compared to the payments that those providers would have otherwise received had the ACA-revised criteria not expired.

E. Indirect Medicare Education (IME) Adjustment

The proposed rule would continue the IME adjustment factor at 5.5 percent for every approximately 10-percent increase in the hospital's resident-to-bed ratio.

CMS proposes to clarify that claims submitted by hospitals for costs associated in providing services to Medicare Advantage (MA) enrollees for IME and direct GME, as well as for nurse and allied health education programs, must meet the claims filing requirements, including timely filing requirements, applicable under regulations at § 424.44 for fee-for-service claims. CMS also proposes to adopt the same policy of meeting the fee-for-service timely claims filing requirements in the case of no pay bills used to calculate the DSH disproportionate patient percentage (DPP) for services furnished on a prepaid capitation basis by an MA organization or through cost settlement with an HMO, competitive medical plan, health care prepayment plan, or a demonstration. CMS does not believe these proposals would have any financial impact.

F. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) and Indirect Medicare Education

To be consistent with its policy change in the FY 2010 IPPS/RY 2010 LTCH PPS final rule which included in the DPP of the Medicare DSH adjustment all *patient days* associated with patients occupying labor and delivery beds once the patient has been admitted to the hospital as an inpatient, CMS proposes to apply the same policy in the *bed day count* for IME and DSH payment adjustments. CMS finds this proposal to be consistent with its policy on observation, swing bed, and hospice days, which are excluded from both the patient day count and available bed count. CMS reminds readers of its policy under which days are excluded of labor and delivery patients who are not admitted to the hospital, and its continued application under this proposed policy revision.

CMS estimates that the impact of including labor and delivery beds in the available bed day count would likely be negligible for DSH purposes (other than for those hospitals that do not currently meet the minimum threshold who may satisfy that criteria by reason of the change), and would decrease IME payments by $170 million in FY 2013.

G. Medicare-Dependent, Small Rural Hospital (MDHs)

CMS notes that the MDH program will expire at the end of FY 2012, and hospitals will be paid based on the Federal rate beginning October 1, 2012.

CMS estimates that MDHs may expect a 6.1 percent decrease in payments. CMS also estimates that 104 MDHs, which are paid under the blended payment of the federal standardized amount and hospital specific rate, will lose approximately $114 million in payments when switched to payment paid only under the Federal standardized amount in FY 2013.

H. Proposed Changes in the Inpatient Hospital Update

CMS proposes a 2.1 percent applicable percentage increase to the FY 2013 operating standardized amount for hospitals that submit required quality data, based on an estimated 3.0 percent market basket increase reduced by 0.8 percentage points for the multifactor productivity (MFP) adjustment and further reduced by 0.1 percentage point under the Act. For hospitals that fail to submit the requisite quality data, the applicable percentage increase would be reduced by an additional 2.0 percentage points resulting in a 0.1 percent increase.

CMS does not propose any changes to its methodology to calculate and apply the MFP adjustment, and bases its market basket update used in determining the applicable percentage increase on IHS Global Insight, Inc. first quarter 2012 forecasts. CMS proposes to use more recent data if available to determine the final market basket update and MFP adjustments.

For SCHs, CMS proposes the same update of 2.1 percent, or 0.1 percent for an SCH that fails to submit requisite quality data, in FY 2013. Similarly, for Puerto Rico hospitals CMS proposes an applicable percentage increase of 2.1 percent to the Puerto-Rico-specific operating standardized amount in FY 2013. As the MDH program is set to expire at the end of FY 2012, CMS would not include MDHs in the update to the hospital specific rates.

I. Payment for Graduate Medical Education Costs

<u>New Teaching Hospitals: Proposed Change in New Program Growth Period from 3 to 5 Years</u>

With respect to hospitals that begin training residents in a new program for the first time on or after October 1, 2012, CMS proposes to extend by 2 years the current 3-year

window in which the hospital may establish and grow new programs. Under this proposal, the new teaching hospital's resident cap would be determined at the end of the fifth year and set permanently effective with the beginning of the sixth program year, and the hospital's cap may be adjusted by the product of 1) the highest number of residents training in any program year during the fifth academic year of the first new program's existence for all new residency programs, and 2) the number of years residents are expected to complete the program, based on the minimum accredited length for the program type involved. Note that CMS proposes to add to the text of its regulations the language in item 2) above to codify its past and current policy.

For new residency training programs where residents are rotating to more than one hospital, CMS would calculate the cap adjustment for each new program started within the 5-year window by determining the product of 1) the highest FTE resident count for residents training in any program year during the fifth academic year at all participating hospitals, and 2) the number of years residents are expected to complete the program (again based on the minimum accredited length for the program type involved). Additionally, CMS would apportion the overall FTE cap among the participating hospitals by taking that product and multiplying it by each hospital's ratio of A) the number of FTE residents in the new program training over the course of the 5-year period at each hospital, to B) the total number of FTE residents training at all participating hospitals over the course of the 5-year period. Thus, CMS would look to the fifth academic year of the first new program to calculate the aggregate cap for the participating hospitals but would consider all 5 years to distribute the aggregate cap among those hospitals.

These proposals respond to concerns expressed by the provider community that 3 years is not a sufficient time to grow residency programs and establish caps that properly reflect the number of FTE residents a hospital will train. CMS is not proposing to change regulations for the treatment of the rolling average and the intern-to-resident bed ratios for new programs.

Assuming 20 possible new teaching hospitals each year, CMS estimates an impact of approximately $175 million over the next 10 years; however, because the proposal would only affect new programs beginning on or after October 1, 2012, CMS believes that no cost would be incurred before FY 2016.

Clarification Related to 5-Year Period Following Implementation of ACA Section 5503 GME FTE Resident Cap Reductions and Increases

In order for a hospital to receive an increase to its FTE resident cap pursuant to redistribution rules enacted in section 5503 of the ACA, the hospital must, among other requirements, 1) maintain the number of primary care residents at or above its average level during the 3 most recent cost reporting ending before enactment of section 5503 (i.e., the primary care average); and 2) ensure that at least 75 percent of the positions attributable to the redistributions are in primary care or general surgery residencies (i.e., the 75-percent threshold). In response to early hospital queries whether and if so how

CMS would enforce the primary care average and 75-percent threshold requirements, CMS responded that the 75-percent threshold requirement applies once the hospital uses any of the section 5503 slots and the primary care average requirement applies on July 1, 2011, regardless of whether the hospital uses its additional slots in year 1 of the 5-year period (July 1, 2011 through June 30, 2016).

CMS now proposes to remove section 5503 slots (IME and direct GME, respectively) from a hospital that fails to fill at least half of those slots in the first, second and/or third cost reporting period of the 5-year period. Note, this test would be determined by cost reporting period—not cumulatively across those cost reporting periods. CMS further proposes that failure to fill slots awarded under section 5503 in a timely manner will also be deemed a failure to meet the 75-percent threshold. (CMS clarifies that the 75-percent threshold applies throughout the 5-year period as long as the hospital uses some amount of its section 5503 slots in the cost reporting period involved.) In the case of this type of failure, Medicare contractors would, after audit, permanently remove all section 5503 slots from the hospital effective back to the earliest cost reporting period that is subject to reopening and for which the hospital failed to satisfy the requirement; CMS notes this would apply even if the hospital used at least half the section 5503 slots in its fourth or fifth cost reporting year of the 5-year period.

CMS further proposes that any hospital receiving section 5503 slots will lose all those slots unless all of them are filled in its final cost reporting period of the 5-year period. CMS bases this policy in part on the fact that hospitals were required in their application for these slots to demonstrate the likelihood of filling them within the first three cost reporting periods and decisions to award slots to hospitals were based in part on those representations. CMS solicits recommendations for alternative approaches to encourage compliance with the primary care average and 75-percent threshold requirements.

CMS proposes that the effective date for these requirements would be a hospital's third 12-month cost reporting period occurring during the 5-year period. CMS does not project any additional costs or savings attributed to these proposals due to budget neutrality.

ACA Section 5506: Preservation of Resident Cap Positions from Closed Hospitals

Generally, section 5506 of the ACA permits the redistribution of residency positions of teaching hospitals that close to other teaching hospitals. The redistribution is to be done in the following priority order (referred to as ranking categories and described in the proposed rule): first to hospitals in the same, or contiguous, CBSA; second to hospitals in the same state; third to hospitals in the same region of the country; and, fourth, if necessary, based on redistribution rules under ACA section 5503. Hospitals must demonstrate that positions will likely be filled within the three academic years that follow the application deadline to receive slots after a particular hospital closes, and any increases are limited to the number of slots from the closed teaching hospital. CMS

in regulations established seven ranking criteria (also described in the proposed rule) for each category in its November 24, 2010 final rule with comment period.

In response to comments, CMS proposes to reduce the deadline by which a hospital must apply for an increase in its FTE cap based on slots from a closed teaching hospital from 4 months following the CMS public notice of the hospital's closing to 60 days after that notice.

CMS notes that the vast majority of applications from the first section 5506 process fell under the seventh (i.e., last) ranking criterion and proposes to add an additional ranking criterion (number eight) which would serve as a catchall and add before it a new seventh criterion for hospitals that 1) do not meet ranking criterion one through six; 2) propose to apply for the slots for primary care or general surgery; and 3) will also apply under the catchall proposed ranking criterion eight (non-primary care/general surgery). CMS believes this is consistent with overall Medicare policy goals to increase residency training in primary care and general surgery.

CMS seeks to clarify, as well as propose a number of changes to, the effective dates for slots awarded under section 5506, and also includes alternative proposals for which it seeks comment. The four effective dates, which vary by ranking criterion, under the first round of section 5506 distributions were 1) the hospital closure date, 2) the cost reporting period (CRP) following the hospital closure date, 3) July 1, and 4) the award announcement date. Below is a table describing the proposed effective dates for future section 5506 distributions:

Ranking Criteria	Temporary Cap Adjustment	Effective Date
One and Three	Yes	CRP beginning after hospital closure
One and Three	No	Hospital closure
Two	No	Hospital closure
Four through Eight	Yes	No earlier than the award announcement; for displaced residents training after the award announcement, July 1 after training complete; no longer retroactive
Four through Eight	No	Award announcement

CMS solicits comments on an alternative effective date policy it is considering for ranking criterion four through eight under which slots would be awarded consistent with hospital need, for example a phase-in over academic years, as shown in the application. CMS also solicits comments on the following effective date issues:

1. Alternative approaches to implement section 5506 with respect to the interaction between the rolling average and the effective dates of retroactive section 5506 slots.
2. Whether the effective dates for all section 5506 slots awarded under all ranking criteria should be prospective.
3. Whether the regulatory temporary cap adjustment for displaced FTE residents displaced from closed hospitals is still necessary and appropriate; or, if it is still

appropriate, whether the exemption from the rolling average for those residents should be eliminated.

CMS clarifies that, in the case of a closed hospital that is training residents in excess of its FTE resident caps, it will not prorate slots among applicant hospitals that qualify under the first, second and third ranking criteria; rather, it will follow the priority under those criteria even in the case where the hospital with ranking criteria one is assigned all the slots to the detriment of a hospital with an affiliation agreement with the closed hospital. CMS believes that a hospital that will assume responsibility for the entire program(s) of a closed hospital (ranking criterion one) is showing a higher degree of commitment than a hospital with an affiliation agreement with the closed hospital (ranking criterion two) which in turn shows a higher degree of commitment than a hospital that seeks to assume a part of an entire program because it does not have the capacity to assume the entire program (ranking criterion three).

CMS also proposes numerous changes to the section 5506 application form itself, including adding the new ranking criterion number seven (described above); prompts to specify whether the application is for a particular program, general cap relief, or for Medicare GME affiliation agreement slots; title changes for the various Demonstration Likelihood Criteria; documentation requirements for unfilled positions; and other, non-substantive changes.

CMS does not project any financial impact for these section 5506 policies and clarifications.

J. Changes to the Reporting Requirements for Pension Costs for Medicare Cost-Finding Purposes

In the FY 2012 IPPS/LTCH PPS final rule, CMS finalized a policy for reporting costs of defined benefit pension plans for purposes of Medicare cost-finding such that, generally, a provider's pension cost equals the cash basis contribution deposits plus carry forward contributions as permitted under the applicable limit for the future period or periods involved. Providers with contributions above the limit may seek approval of the excess contributions. CMS proposes to make conforming changes to other existing regulations governing general cost reporting rules under §§ 413.24 and 413.100 to account for the exception for recognizing actual pension contributions funded during the cost reporting period on a cash, rather than on an accrual, basis. Because the changes are largely conforming in nature, CMS does not project any financial impact on hospitals for FY 2013.

K. Rural Community Hospital Demonstration Program

For the 23 hospitals participating in the budget neutral, rural community hospital demonstration program in FY 2013, CMS proposes a simpler and more accurate 3-step methodology to calculate the budget neutrality offset amount that is applied across aggregate IPPS payments. Under the proposal, CMS would calculate the budget neutrality offset amount by subtracting the sum of estimated aggregate amount of

payments to all 23 hospitals participating in the demonstration program for covered inpatient hospital services that would otherwise be made in the absence of the demonstration (calculated under Step 2 of the methodology) from the aggregate reasonable cost amount payments to all 23 hospitals for those services estimated to be made under the demonstration (calculated under Step 1 of the methodology).

CMS proposes several changes to its methodology. It would:

1. Use hospital data for all participating hospitals from "as submitted" cost reports rather than a mix of "as submitted" and "settled" cost reports, as had been used for FY 2012.
2. Update the estimated reasonable cost amounts for all 23 hospitals under the demonstration by the IPPS market basket percentage increase (Step 1 of the methodology).
3. Update the estimated payments that would otherwise be made to those 23 hospitals absent the demonstration by the applicable percentage increase, rather than by the market basket percentage increase (Step 2 of the methodology).

CMS estimates that the amount of the adjustment to the national IPPS rates during FY 2013 is $35,077,708, and notes that it would use updated data for the final rule if available. CMS also notes that if settled cost reports are available for all hospitals participating in FY 2007 through 2010 before the FY 2013 final rule, it will include in the budget neutrality offset for FY 2013 any additional amounts by which the final settled cost reports for one or more of those fiscal years exceeded the budget neutrality offset amount for fiscal year involved.

L. Hospital Routine Services Furnished under Arrangements

In the FY 2012 IPPS/LTCH PPS final rule, CMS revised its policy under which a hospital may furnish services under arrangements stating that only therapeutic and diagnostic services may be furnished under arrangements. Routine services (bed and board, or nursing services and other related services) may not be provided under arrangements. CMS proposes to delay the implementation date of its revised policy one-year to cost reporting periods beginning on or after October 1, 2013, but CMS cautions hospitals that it expects full compliance at that time. CMS believes the financial impact of the proposed effective date change would be negligible.

M. Proposed Technical Change

CMS proposes a technical conforming change to the text of its regulations at § 413.79(f)(7) with respect to the length of emergency Medicare GME affiliation agreements which was increased to 5 years in the aftermath of Hurricanes Katrina and Rita. CMS proposes to reflect that increase to
5 years in subclause (i)(B) of § 413.79(f)(7) for consistency with the rest of that section.

V. Proposed Changes to the IPPS for Capital-Related Costs

Capital Standard Rate for FY 2013. The annual update to the payment rates for capital-related costs for FY 2013 is 1.3 percent based on the capital input price index (CIPI). CMS, however, proposes to apply a 0.8 percentage point reduction in the national capital federal rate to reflect changes which occurred in FY 2010 in documentation and coding changes that do not reflect real changes in case mix in light of the adoption of MS-DRGs. In previous regulations, CMS adjusted the national capital federal rate to account for case-mix changes occurring in FY 2008 and FY 2009.

CMS proposes the national capital federal rate for FY 2013 at $424.42, representing a 0.71 percent change from FY 2012, calculated as follows:

- The update factor of 1.0130—a 1.3 percent increase
- The budget neutrality factor of 1.002 for changes in MS-DRG classifications and relative weights and in the geographic adjustment factors—a 0.02 percent increase
- The outlier adjustment factor of 0.9400—a 0.19 percent decrease compared to the FY 2012 outlier offset
- The cumulative adjustment factor for MS-DRG documentation and coding adjustment of 0.9404, a 0.79 percent decrease compared to the FY 2012 cumulative adjustment of 0.9479

The net impact of the proposed rule is an estimated 0.2 percent decrease in average capital payments per discharge from FY 2012 to FY 2013 for all hospitals. On average, all hospitals, urban and rural combined, are expected to experience a decrease in average capital IPPS payments per case in FY 2013 as compared to FY 2012. Capital IPPS payments per case for urban hospitals are projected to decrease 0.2 percent, while rural hospitals are projected to experience no change in average payments. Lower average payments are projected despite the 0.71 percent rate increase due to an expected decrease in outlier payments in FY 2013 and somewhat lower geographic adjustment factors.

For Puerto Rico hospitals, the proposed FY 2013 special capital rate is $206.82 compared to $203.86 in FY 2012.

Exception Payments. The IPPS for capital-related costs was first implemented in the FY 1992 with a 10-year transition period. CMS notes that while the exception payments were first instituted during the 10-year transition period which ended in 2001 (referred to as regular exceptions), for eligible hospitals these exception payments are available within the subsequent 10 years following the end of the transition period (referred to as special exceptions). CMS notes that there are no hospitals remaining that qualify for special exceptions payments in FY 2012, and that after FY 2012 no payments may be made to any hospital under the special exceptions authority.

The regulations provide that a hospital may request an additional payment if the hospital incurs unanticipated capital expenditures in excess of $5 million due to extraordinary circumstances beyond the hospital's control.

New Hospitals. Medicare defines a "new hospital" as a hospital that has operated for less than 2 years. CMS notes that a new hospital beginning on or after October 1, 2002 would be paid 85% of its Medicare allowable capital-related reasonable costs through the first 2 years of operation unless the new hospital elects to receive full prospective payment based on 100 percent of the Federal rate.

VI. Proposed Changes for Hospitals Excluded from the IPPS

CMS proposes a 3.0 rate-of-increase percentage to the target amount for cancer hospitals, children's hospitals, and religious nonmedical health care institutions (RNHCIs), unless more recent data is available for the final rule. CMS proposes to use the percentage increase in the IPPS operating market basket because the number of cancer hospitals, children's hospitals, and RNHCIs is too small and cost report data too limited to create a market basket for them. These hospitals and institutions are not subject to the ACA-mandated percentage point reductions for the MFP or the statutory 0.1 percentage point reduction applicable to IPPS hospitals.

CMS notes that the annual updates for IRF PPS and IPF PPS are issued separately.

VII. Proposed Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2013

Overview

The table below summarizes CMS' proposals for the LTCH PPS for FY 2013.

Summary of Estimated Impact of Proposed Changes to LTCH PPS for FY 2013	
Proposed key update factors	
Market basket change	+3.0%
Multi-factor productivity adjustment	-0.8%
Additional adjustment required by statute	-0.1%
Net market basket update	**+2.1%**
One-time budget neutrality adjustment for base year estimates (1st year of 3-year proposed phase-in), for discharges on or after 12/29/2012	-1.3%
Standard Federal Rate	
FY 2012	$40,222.05
FY 2013, proposed	
Discharges from 10/1/2012 – 12/28/2012	$41,026.88
Discharges from 12/29/2012 – 9/30/2013	$40,507.48
Estimated changes in total payments (in billions)	
Spending, FY 2012	$5.181
Spending, FY 2013	$5.282.
Change, FY 2012-FY2013	+$0.101l

Summary of Estimated Impact of Proposed Changes to LTCH PPS for FY 2013	
Estimated percent change in payments per discharge*	
All LTCH providers (427 LTCH providers)	+1.9%
Rural (27 LTCH providers)	+3.6%
Urban (400 LTCH providers)	+1.9%
Voluntary (82 LTCH providers)	+2.6%
Proprietary (322 LTCH providers)	+1.8%
Government (14 LTCH providers)	+1.8%
Unknown ownership (9 LTCH providers)	+3.0%
*More detail on the changes in payments per discharge is available in Table IV of "J. Effects of Proposed Payment Rate Changes and Policy Changes under the LTCH PPS"	

CMS proposes updates for LTCHs using a process generally consistent with prior regulatory policy, and notes several changes:

- CMS proposes implementation of an LTCH-specific market basket for FY 2013, **with a request for comment on the approach.**
- CMS proposes continuation for one additional year of the moratorium on full implementation of the "25 percent threshold" payment adjustment.
- CMS proposes an end to the moratorium on use of the IPPS Comparable Per Diem Amount Payment Option for Very Short Stays under the Short-Stay Outlier (SSO) Policy, for discharges occurring on or after December 29, 2012.
- CMS proposes an adjustment (of approximately -3.75 percent) to the standard federal rate (proposed to be phased-in over a three-year period) to reflect the agency's determination that the initial budget neutrality calculation for FY 2003 was not sufficient, and its standing policy that any discrepancies in that year not be perpetuated for future years. This proposed adjustment has been delayed by regulation and statute in the past. It is applicable for discharges occurring on or after December 29, 2012 upon expiration of the current moratorium.

A. Proposed Medicare Severity Long-Term Care Diagnosis-Related Group (MS-LTC-DRG) Classifications and Relative Weights for FY 2013

Patient Classification into MS-LTC-DRGs

CMS continues to use the same Medicare Severity Diagnosis-Related Groups (MS-DRG) classification system used for the IPPS payments for the LTCH PPS (MS-LTC-DRG). As noted elsewhere in this summary, CMS is not proposing to add or delete any MS-DRGs this year, retaining the 751 in place for FY 2012. The other updates to the MS-DRG system described elsewhere in this summary would be reflected in the MS-LTC-DRG system since it is the same classification system.

Relative weights in the MS-LTC-DRGs

In computing the relative weights, CMS proposes to continue is prior policy to exclude data of 14 all-inclusive rate providers, 2 LTCHs that are paid in demonstration projects, and all Medicare Advantage claims.

CMS proposes to continue two long-standing policies for setting the relative weights of the MS-LTC-DRGs in a manner different from the IPPS.

- CMS proposes to continue to calculate the relative weights based on LTCH facilities alone (rather than using the IPPS relative weights) to reflect the different resource use and costs of such patients compared with the broader IPPS system.
- CMS proposes to continue to set the relative weights based on a hospital-specific relative-value (HSRV) methodology, because CMS finds that LTC facilities often specialize in certain services that have the potential to distort charge differences among facilities.

Volume-related adjustments

CMS proposes to continue to account for low-volume MS-LTC-DRG cases in updating the MS-LTC-DRG relative weights as follows:

- If a proposed MS-LTC-DRG has at least 25 cases, it is assigned its own proposed relative weight (there are 231 such MS-LTC-DRGs).
- If a proposed MS-LTC-DRG has 1-24 cases, is assigned to one of five quintiles based on average charges (CMS finds that there are 307 such MS-LTC-DRGs). CMS then determines a proposed relative weight and average length of stay of the MS-LTC-DRGs in the quintile and applies them to each MS-LTC-DRGs in the quintile.
- If a proposed MS-LTC-DRG has zero cases (CMS finds that there are 213 such MS-LTC-DRGs), it is cross-walked to another proposed MS-LTC-DRG based on clinical similarities in intensity of use and costliness of resources, in order to assign an appropriate proposed relative weight. If the MS-LTC-DRG that is similar is a low-volume DRG that has been assigned to one of the five quintiles noted above, then the zero volume MS-LTC-DRG would be assigned to that same quintile. CMS further notes that it will assign a 0.0 relative weight for eight transplant MS-LTC-DRGs because Medicare coverage policy covers these procedures only in a certified hospital, and no LTCH has been so certified.

Determining the Relative Weights

After grouping the cases as noted, CMS proposes to continue its policy of calculating the relative weights by first removing statistical outliers (charges outside of 3.0 standard deviations from the mean) and cases with a length of stay of 7 days or less. It then adjusts for the effect of short-stay outlier (SSO) cases. It proposes to continue to adjust for SSO cases by counting an SSO as a fraction of a discharge based on the ratio of the length of stay of the SSO case to the average length of stay for the MS-LTC-DRG for non-SSO cases.

Budget Neutrality Factor

Consistent with prior policy, CMS proposes a budget neutrality adjuster for the annual update to the MS-LTC-DRG classifications and relative weights. That adjuster first includes a normalization adjustment of 1.12393 that CMS applies to the recalculated relative weights to ensure that the recalibration does not change the average case mix index. It then proposes a budget neutrality adjustment of 0.9881603.

Tables

Table 11 in Section VI of the Addendum lists detailed information for each of the MS-LTC-DRGs.

B. Proposed Use of a LTCH-Specific Market Basket under the LTCH PPS

CMS notes that the initial market basket for the LTCH PPS in FY 2003 was the "excluded hospital with capital" market basket. Starting with rate year 2007, CMS updated LTCH PPS payments using a market basket reflecting operating and capital costs of Inpatient Rehabilitation Facilities, Inpatient Psychiatric Facilities, and LTCHs (this is referred to as the Rehabilitation, Psychiatric and LTCH market basket, or the RPL market basket).

CMS previously (in 2010) noted its interest in exploring a stand-alone LTCH market basket, and now proposes such an LTCH market basket for FY 2013. **CMS seeks comments on the proposed methodology for determining an LTCH-specific market basket.**

CMS proposes to use FY 2009 Medicare LTCH cost reports, but only from facilities that have a Medicare average length of stay within a comparable range (+/- 15 percent) of the facility's total average length of stay.

CMS proposes to first calculate cost weights for six cost categories based on the cost reports: Wages and Salaries, Employee Benefits, Contract Labor, Professional Liability Insurance, Pharmaceuticals, and Capital, as well as a "Residual". It proposes to supplement the data using the Bureau of Economic Analysis 2002 Benchmark Input-

Out Tables to create more detailed hospital expenditure category shares. CMS notes that these are the same data used to derive most of the other PPS CMS market baskets.

CMS proposes to assign price proxies as with other market baskets, using, as appropriate for the category, Producer Price Indexes (PPI), Consumer Price Indexes (CPI), and Employment Cost Indexes (ECIs).

Table VII.C-2 in the proposed rule details the proposed categories and weights, and how they compare with the current RPL weights, along with the proposed price proxies. The summary table below sets out differences between the current weights for major categories (not all subcategories) based on the FY 2008-Based RPL market basket and the proposed FY 2009-Based LTCH market basket. Table VII.C-2 should be consulted for detail on all the categories and subcategories and the proposed price proxies.

Proposed FY 2009-Based LTCH Specific Weights for Major Cost Categories, Compared with Current FY 2008-Based RPL Weights		
Major Cost Categories	**Proposed FY 2009-Based LTCH Specific Weights**	**Current FY 2008-Based RPL Weights**
Compensation	**54.338**	**62.278**
Wages and Salaries*	46.330	49.447
Employee Benefits*	8.008	12.831
Utilities	**1.751**	**1.578**
Professional Liability Ins.	**0.830**	**0.764**
All Other Products and Services	**33.252**	**26.988**
All Other Products	19.531	15.574
All Other Services	13.721	11.414
Capital-Related Costs	**9.829**	**8.392**
Total	**100.0**	**100.0**
Summarized from Table VII.C-2 *Note: contract labor is distributed to wages and salaries and employee benefits based on the share of total compensation that each category represents		

CMS sets out detailed specifications for each cost category and each price proxy that is proposed for the LTCH-specific market basket.

Proposed Market Basket Update

For FY 2013, using the proposed LTCH-specific market basket, CMS projects a market basket update of 3.0 percent based on the IHS Global Insight 2011 and first quarter 2012 forecast (this is the same firm that forecasts components of other market baskets for CMS.) CMS notes that, as with all proposed market basket updates, if more recent data become available it would use such data for the FY 2013 update in the final rule. CMS sets out in Table VII.C-5 a comparison between the FY 2008-based RPL market

basket and the proposed FY 2009-Based LTCH-specific market basket. That table is summarized below.

FY 2008-Based RPL Market-Basket Index and Proposed FY 2009-Based LTCH Market Basket, Percent Changes		
	Market-Basket Index Percent Change	
Fiscal Year	FY 2008-Based RPL Index	Proposed FY 2009-Based LTCH Index
Historical Average, 2008-2011	2.8	2.9
Forecast		
2012	2.4	2.5
2013	3.0	3.0
2014	3.1	3.1
2015	3.2	3.1
Forecast Average 2012-2015	2.9	2.9
Summarized from Table VII.C-5		

Proposed FY 2013 Labor-Related Share

CMS sets out a proposed labor-related share of 63.217 percent based on the most recent IHS Global Insight projection for purposes of applying the area wage index. It reviews the detailed categories included, and sets out in Table VII.C-6 a comparison with the labor-related share of 70.199 for FY 2012 based on the RPL market basket. That table is reproduced below.

Comparison of FY 2012 Relative Importance Labor-Related Share Based on the FY 2008-Based RPL Market Basket and the Proposed FY 2013 Relative Importance Labor-Related Share Based on the Proposed FY 2009-Based LTCH Market Basket		
	FY 2012 Relative Importance Labor-Related Share (1)	Proposed FY 2013 Relative Importance Labor-Related Share (2)
Wages and Salaries	48.984	45.604
Employee Benefits	12.998	8.143
Professional Fees: Labor-Related	2.072	2.216
Administrative and Business Support Services	0.416	0.502
All Other: Labor-Related Services	2.094	2.513
Subtotal	66.564	58.978
Labor-Related Portion of Capital Costs (46%)	3.635	4.239
Total Labor-Related Share	**70.199**	**63.217**
Table VII.C-6		

Comparison of FY 2012 Relative Importance Labor-Related Share Based on the FY 2008-Based RPL Market Basket and the Proposed FY 2013 Relative Importance Labor-Related Share Based on the Proposed FY 2009-Based LTCH Market Basket
(1) FY 2012 IPPS/LTCH PPS Final Rule; First Quarter 2012 IHS Global Insight Forecast

C. Proposed Changes to the LTCH Payment Rates for FY 2013 and Other Proposed Changes to the LTCH PPS for FY 2013

Proposed Annual Market Basket Update

CMS proposes a full market basket update of 3.0 percent, based on the proposed new LTCH market basket described above, with several adjustments.

- CMS proposes a 0.8 percent adjustment for the multi-factor productivity adjustment called for under the ACA.
- CMS proposes to subtract the additional adjustment of 0.1 percentage point called for under sections 1886(m)(3)(A)(ii) and 1866(m)(4)(C).

That yields a proposed update of 2.1 percent for FY 2013.

COLA Updates for Alaska and Hawaii

CMS proposes to continue to use "frozen" COLA factors used in FY 2012 for FY 2013, and to update the COLA factors for Alaska and Hawaii beginning in FY 2014 based on a comparison of the growth in the CPIs for Anchorage, Alaska and Honolulu, Hawaii with the growth in the CPI for the average U.S. city. The proposed approach would continue to use the statutorily mandated cap of 25 percent on the adjustments. Finally, CMS proposes to update the COLA factors every four years, starting with FY 2014.

D. Expiration of Certain Payment Rules for LTCH Services and the Moratorium on the Establishment of Certain Hospitals and Facilities and the Increase in Number of Beds in LTCHs and LTCH Satellite Facilities

The 25 Percent Payment Adjustment Threshold

CMS proposes to extend the existing delay of the full implementation of the 25 percent payment adjustment threshold for an additional year (for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013.) CMS notes that the threshold was put in place because research revealed a strong correlation between growing numbers of discharges from IPPS hospitals, after short-stays, to onsite or neighboring LTCHs, yielding costs to Medicare. CMS now proposes this additional extension because it believes that it could be in a position in the near future to propose revisions to payment policy that would render that threshold unnecessary, based in part on prior MedPAC and CMS research cited by CMS in the preamble.

The "IPPS Comparable Per Diem Amount' Payment Option for Very Short Stays under the Short-Stay Outlier (SSO) Policy

The 5-year moratorium on application of the IPPS comparable per diem amount as one option under the Short-Stay-Outlier (SSO) payment adjustment is scheduled to expire for discharges occurring on or after 12/29/2012. CMS does not propose to extend the moratorium, at which point this option becomes one of the payment options included in the list of options from which CMS selects the least costly alternative in paying for an SSO discharge. CMS also proposes to clarify that the IPPS comparable per diem amount is capped at an amount comparable to what would have been full payment under the IPPS.

Proposed One-Time Prospective Adjustment to the Standard Federal Rate

In the August 2002 Final Rule, CMS set LTCH PPS rates to achieve budget neutrality for FY 2003 with the prior TEFRA-based system, and also stated its intent to provide for a prospective, one-time adjustment if future data indicated that the original budget neutrality calculation for payments in FY 2003 yielded rates that were too high or too low. The original deadline for that adjustment has been extended, and subsequently the Congress set and then extended a moratorium on implementing the adjustment. The current moratorium expires on December 28, 2012.

CMS now proposes to implement this adjustment starting during FY 2013, for discharges occurring on or after December 29, 2012. The methodology has been discussed in previous proposed rules and the methodology and specific calculation steps, and adjustments, are set out in detail in these proposed rules.

The result is that CMS finds that the budget neutrality adjustment originally built into the FY 2003 payment rates was not adequate, and proposes that it would need to apply a factor of 0.9625 (a reduction of about 3.75 percent) to payments in FY 2013 to assure that the original miscalculation is not retained in future payment rates. CMS proposes to make this adjustment over three years applying a factor of 0.98734 for FY 2013 (a reduction of about 1.3 percent) to payments for discharges occurring on or after December 29, 2012.

VIII. Proposed Quality Data Reporting Requirements for Specific Providers and Suppliers

This section of the proposed rule addresses several different quality-related programs. Changes are proposed to the existing inpatient hospital quality reporting program and the inpatient hospital value-based purchasing program which has been finalized in previous rulemaking for initial implementation in FY 2013. Additional requirements are proposed for the long-term care hospital quality reporting program which will be implemented in FY 2014, and the ambulatory surgical center quality reporting program which will begin in CY 2014. Finally, two new quality reporting programs are proposed

in this rule, one for PPS-exempt cancer hospitals and the other for inpatient psychiatric facilities.

A. Hospital Inpatient Quality Reporting (IQR) Program

This section of the rule discusses requirements for the Hospital IQR Program, including a number of proposed changes. (An IPPS hospital that chooses not to participate in the IQR program or that one fails to meet the requirements of the program for a fiscal year will receive an update factor reduction of 2.0 percentage points.) Removals and additions to the Hospital IQR Program measure set are proposed beginning with the FY 2015 payment determination, and other changes to the procedures for hospital reporting are proposed. **A chart displaying the previously adopted and proposed measures for the FYs 2014, 2015 and 2016 payment determinations begins on page 78.**

Maintenance of Technical Specifications for Quality Measures

Many quality measures adopted for use in the Hospital IQR Program have been endorsed by the National Quality Forum (NQF) and subject to NQF's regular measure maintenance procedures.
CMS proposes that if NQF updates an endorsed measure that has been adopted for the Hospital IQR Program, a subregulatory process would be used to incorporate the updates into the measure specifications used in the program. The Specifications Manual would be revised and updates would be posted on the QualityNet.org website. CMS states that where changes to hospital data collection systems are needed, it would provide hospitals with "sufficient lead time" to implement the changes. CMS proposed to use the rulemaking process to adopt changes that it considers to "substantially change the nature of the measure." CMS believes this strikes the proper balance between expeditiously incorporating NQF updates into measures that are in use in the Hospital IQR Program and allowing opportunity for public comment.

Removal and Suspension of Hospital IQR Program Measures

CMS has in past rulemaking used the term "retire" to refer to the removal of a measure from the Hospital IQR Program measure set. In order to avoid the implication that CMS recommends that other payers should also stop using a measure, CMS will use the term "remove" rather than "retire" with respect to measures that are no longer included in the program.

Since the IQR program began, seven measures have been removed. Four of these measures are in effect for the FY 2013 payment determination, but data collection was suspended as of January 1, 2012 and they will not be part of the IQR for payment determinations for FY 2014 or later. These measures are AMI-4: Adult smoking cessation advice/counseling; HF-4: Adult smoking cessation advice/counseling; PN-4: Adult smoking cessation advice/counseling, and PN-5c: Timing of receipt of initial antibiotic following hospital arrival.

In previous rulemaking, data collection on an additional four measures has been suspended because hospital performance on the measures was considered "topped out." These are: AMI 1: Aspirin at arrival, AMI-3: Angiotensin Converting Enzyme Inhibitor or Angiotensin II Receptor Blocker for left ventricular systolic dysfunction, AMI-5: Beta blocker prescribed at discharge, and SCIP-Inf-6: Surgery patients with appropriate hair removal. In contrast to the measures that were removed from the program, data collection on a suspended measure could be resumed if CMS determines that performance on the measures has declined. Hospitals would be given at least 3 months notice prior to resumption of data collection.

In this rule, CMS proposes to remove 17 measures from the Hospital IQR Program beginning with the FY 2015 payment determination. The measure "SCIP-VTE-1: Surgery patients with recommended VTE prophylaxis ordered" is proposed for removal because CMS believes that another measure currently used in the program, "SCIP-VTE-2: Surgery patients who received appropriate VTE prophylaxis within 24 hours of pre/post surgery," assesses practices that are more proximal in time to better surgical outcomes from the use of VTE prophylaxis. CMS also notes that in a recent NQF maintenance review of this measure, it was not recommended for continued endorsement.

The other 16 measures proposed for removal are the eight hospital acquired condition (HAC) measures and eight Agency for Healthcare Research and Quality (AHRQ) measures. CMS offers several reasons for removing the HAC measures from the Hospital IQR Program, including redundancy with other measures and a recommendation from the Measure Application Partnership (MAP) to replace the HACs with NQF-endorsed measures. (As discussed below, the MAP is a multi-stakeholder group convened by the NQF.) Public reporting of the HACs will continue to be required under section 3008 of the Affordable Care Act, and CMS states that the HACs remain important to CMS' commitment to measuring patient harm and safety.

The AHRQ measures proposed for removal include five patient safety indicator (PSI) measures and three inpatient quality indicators (IQIs). (The summary table at the end of this section lists all the measures proposed for removal.) The PSI measures are proposed for removal because four of them are included in the complication/patient safety composite measure that is also in the Hospital IQR Program, and CMS believes that the fifth measure, regarding post-operative respiratory failure, could be captured in the near future using the National Healthcare Safety Network. CMS states that the three IQI measures proposed for removal overlap with the 30-day mortality measures that are included in the program and which the MAP recommended for use in the Inpatient Hospital VBP Program. Thus, the proposal would reduce measure redundancy within the IQR program and would retain the measures that would be used in the VBP program.

Additional Hospital IQR Program Measures for the FY 2015 Payment Determination and Subsequent Years

CMS reviews the criteria it uses in adopting measures for use in the IQR program, emphasizing support for the National Quality Strategy triple aims (better health care for individuals, better health for populations, and lower health care costs) and indicating that the statutory requirements under section 1890A(a)(4) of the Act as added by the ACA required the Secretary to consider input from multi-stakeholder groups in selecting measures. The MAP is a partnership of multi-stakeholder groups convened by NQF to provide input on measures and CMS will consider the recommendations of the MAP in selecting quality and efficiency measures. Among other considerations is selection of measures that will meet the VBP program inclusion criteria.

For the purposes of streamlining the rulemaking process, CMS proposes that once a measure is adopted for the Hospital IQR Program for a payment determination year it will automatically be adopted for subsequent years until CMS proposes to remove, suspend or replace it. In previous rulemaking, CMS has proposed to retain previously adopted measures on a year-by-year basis.

CMS proposes to add several measures to the Hospital IQR Program for the FY 2015 payment determination and future years. These include expansion of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) patient experience survey, and addition of new measures for complications of hip and knee surgery, hip/knee readmissions, hospital-wide readmissions, and elective delivery prior to 39 completed weeks gestation. **In addition, CMS makes a proposal regarding current IQR program measures for which NQF specifications have been changed.** The measures involved are Central Line-Associated Blood Stream Infections (CLABSI) and Catheter-associated urinary tract infections (CAUTI).

Expansion of HCAHPS to include Care Transitions Measure. **CMS proposes to expand the HCAHPS survey to include a 3-part Care Transition Measure which has been endorsed by the NQF and recommended by the MAP for immediate inclusion to the Hospital IQR Program.** The measure meets the protocols for addition to the HCAHPS. The specific wording proposed by CMS for use in the Hospital IQR Program differs slightly from the wording in the measure as endorsed by the NQF. CMS indicates that the measure developer has agreed to the modifications and CMS believes these are consistent with the NQF endorsement. The proposed additional questions, as modified by CMS, are:

- During this hospital stay, staff took my preferences and those of my family or caregiver into account in deciding what my health care needs would be when I left.
- When I left the hospital, I had a good understanding of the things I was responsible for in managing my health.
- When I left the hospital, I clearly understood the purpose for taking each of my medications.

For each question, the patient could respond "strongly disagree," "disagree," "agree," or "strongly agree." For the last question regarding medications, the patient could also answer that they were not given any medications when they left the hospital.

Addition of "About You" Questions to HCAHPS. **CMS also proposes to add two questions to the "About You" section of the HCAHPS required for collection beginning January 1, 2013.** One yes/no question would ask "During this hospital stay, were you admitted to this hospital through the Emergency Room?" and the other would ask "In general, how would you rate your overall mental or emotional health." CMS indicates the reason for asking the question about admission through the emergency room is that this information was collected until June 2010 from hospitals as an administrative code and was used as a patient-mix adjustment for HCAHPS scores. CMS found this variable to be meaningful and adding the question to the HCAHPS would allow CMS to again use emergency room admission as a patient-mix adjustment variable. The proposed rule links to an analysis of this HCAHPS adjustment: http://www.hcahpsonline.org/files/Final%20Draft%20Description%20of%20HCAHPS%20Mode%20and%20PMA%20with%20bottom%20box%20modedoc%20April%2030,%202008.pdf.
With respect to the second proposed question on mental health status, CMS indicates that it has received numerous requests from hospitals and researchers to add such a question, and that some researchers believe that mental health status is an important factor in how patients respond to the HCAHPS survey questions.

Hip/Knee Surgical Complications. **CMS proposes to add a new measure, "Hip/Knee Complication: Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthoplasty (THA) and Total Knee Arthoplasty (TKA),"** which is an NQF-endorsed measure (NQF #1550) and one that was recommended by the MAP for inclusion in the Hospital IQR Program. In proposing the addition of this measure, CMS cites data on the high and rising volume and cost of these procedures and cites that the clinical literature which CMS reports has found high rates of serious post-operative complications for these procedures.

The measure uses Medicare claims data to assess complications occurring after THA and TKA surgery from the date of the index admission and 90 days thereafter. One or more of the following complications are measured: acute myocardial infarction, pneumonia, or sepsis/septicemia within 7 days of admission; surgical site bleeding, pulmonary embolism or death within 30 days of admission; or mechanical complications, periprosthetic joint infection or wound infection within 90 days of admission. CMS reports that the median hospital-level risk-standardized complication rate for 2008 was 4.2 percent, with a range from 2.2 percent to 8.9 percent, and that this range across hospitals suggests potential for quality improvement.

The measure includes Medicare beneficiaries age 65 and older who have had continuous enrollment fee-for-service Medicare coverage in the 12 months prior to the index admission. In the proposed rule CMS discusses the clinical exclusions and further

details of the measure specifications, which can be found on the qualityforum.org website or through this link **http://tinyurl.com/7lzzje5 .**

CMS notes that the measure uses the same hierarchical logical modeling (HLM) methodology that is specified for other outcome measure included in the Hospital IQR Program, namely the readmission and mortality measures for heart attack, heart failure and pneumonia. The risk adjustment approach defines risk factors using the Hierarchical Condition Categories (CC). The proposed rule indicates that the CCs used in the risk adjustment model for this measure are available on the qualitynet.org website. (The link provided in the rule appears to be broken, but a search for measure NQF 1550 will produce a text file crosswalk of ICD-9-CM and CC crosswalk for the measure which is used to adjust for patient risk factors.)

Hip/Knee Readmissions. **CMS also proposes to add another hip/knee related measure: "Hip/Knee Readmission: Hospital-Level 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Total Hip Arthoplasty (THA) and Total Knee Arthoplasty (TKA),"** which is NQF-endorsed (NQF #1551) and was recommended by the MAP for inclusion in the Hospital IQR Program. CMS estimates using 2008 Medicare fee-for-service claims data that the mean risk-standardized readmission rate calculated under this measure to be 6.06 percent, ranging from 3.06 to 50.94 percent, which it believes means there is room for improvement.

The measure is a Medicare claims based measures similar to the existing readmission measures. Like the other readmission measures and the proposed hip/knee complications measure, the HLM methodology for risk adjustment is used for this hip/knee readmissions measure. (The qualitynet.org website includes a crosswalk to CCs used in the risk adjustment model for this measure.) Readmissions associated with a subsequent planned THA/TKA procedures within 30 days of discharge from the index hospitalization are excluded from this measure. In the proposed rule CMS discusses other exclusions and further details of the measure specifications, which can be found on the qualityforum.org website or through this link http://tinyurl.com/cy37xon. The proposed rule does not discuss whether the hospital performance rate on this measure that will be reported on *Hospital Compare* will be calculated using data for a single year or for three years, like the existing readmission measures for heart attack, heart failure and pneumonia.

Hospital-wide Readmissions. **CMS proposes to add a measure of hospital-wide readmissions to the Hospital IQR Program.** The proposed rule discusses evidence regarding rates of preventable readmission, with overall rates estimated to range from 12 percent to 76 percent of readmissions, and literature tying readmissions to quality of care. CMS notes that the existing readmission measures related to heart attack, heart failure and pneumonia account for a relatively small proportion of total readmissions.

The specific Hospital-wide Readmission (HWR) measure proposed was developed by CMS using 2008 Medicare fee-for-service data and is undergoing NQF review (tentative NQF #1789). The MAP supported inclusion of this measure in the IQR

program subject to NQF endorsement. CMS expects that NQF endorsement will be finalized in coming months. Regardless, CMS proposes to adopt this measure under the exceptions authority that allows the inclusion of measures that are not NQF endorsed.

The proposed rule discusses the specifications for the measure in some detail. Briefly, the measure reflects all-cause unplanned readmissions for Medicare beneficiaries age 65 and older within 30 days following an index admission. Exclusions, which are detailed in the proposed rule and specifications, include patients undergoing medical treatment for cancer and primary psychiatric disease as well as deaths and transfers. An algorithm is used to identify admissions that are likely to be planned. It is based on the assumption that, depending on the discharge condition, readmissions which include any of a specified list of procedures or for maintenance chemotherapy are considered to be a planned readmission while readmissions for acute illness or complications of care are unplanned readmissions. Both the list of procedure categories considered planned and the list of acute conditions and complications of care are included in the proposed rule. The measure specifications and other information pertinent to the NQF review of measure #1789 can be found at http://www.qualityforum.org/Projects/Readmissions_Endorsement_Maintenance.aspx#t=2&s=&p=5%7C3%7C7%7C.

CMS describes in the proposed rule how, in calculating this measure, Medicare claims data is used to compute a single summary score that is derived from scores for five separate specialty cohorts: medicine, surgery/gynecology, cardiorespiratory, cardiovascular, and neurology. For each cohort, risk adjusted predicted and expected readmissions are calculated for each hospital. A single summary score is calculated as the volume-weighted log average of the predicted over expected ratios from each cohort, multiplied by the national average readmission rate. CMS notes that because this measure applies to Medicare discharges broadly, only one year of claims data is required to calculate this measure rather than the three years used for the heart attack, heart failure and pneumonia readmission measures, which require the additional data to increase the sample size.

Perinatal Care Measure. CMS proposes to add a measure related to perinatal care, a category for which the IQR program currently has no measures. The proposed rule includes a discussion of the problems associated with preterm births and the HHS Strong Start Initiative aimed at reducing the rate of preterm births. CMS notes that in 2011, Medicare paid for about 14,000 births and that many women under age 44 who are Medicare beneficiaries are dually eligible for Medicare and Medicaid.

Specifically, CMS proposes to add "Percentage of Babies Electively Delivered Prior to 39 Completed Weeks Gestation", a measure that is NQF-endorsed (NQF# 0469) and was recommended by the MAP for inclusion in the IQR program. The measure would assess the percent of patients with deliveries (vaginal and Cesarean) at >= 37 and < 39 weeks completed gestation with a procedure code for 1) medical induction of labor or 2) Cesarean section while not in active labor or experiencing spontaneous rupture of membranes. Detailed measure specifications are available at

http://manual.jointcommission.org/releases/TJC2012A/MIF0166.html.

CMS proposes that this chart-abstracted measure be reported in the aggregate using a web-based tool. Hospitals would provide aggregate numerator, denominator and exclusion counts, as discussed below in the section on form, manner and timing of quality data submission. CMS also indicates that it expects e-specifications for this measure will be complete in the summer of 2012 and will move to electronic health record (EHR)-based collection of this measure once the infrastructure to do so is in place.

Clarifications Regarding CLABSI and CAUTI Measures. CMS reports that as part of NQF measure maintenance review, two existing IQR program measures have recently been re-specified. In particular, the CLABSI and CAUTI measures which were limited to ICU cases have been expanded to include non-ICU hospital locations and other care settings. **Despite the expansion of the CLABSI and CAUTI measures at NQF, CMS proposes that the Hospital IQR Program requirement continue to be that hospitals submit data for these two measures on ICU locations only.** As noted below, CMS intends to propose collection of data on these measures in the future. **CMS seeks comment on the feasibility and timing of expanding data collection for acute care hospitals beyond the ICU.** CMS also notes that the NQF changed the calculation of these measures and is now using a standardized infection ratio (SIR), which is consistent with how CMS has been reporting these data on the *Hospital Compare* website, so this change at NQF will not affect the Hospital IQR Program.

Additional Hospital IQR Program Measure for the FY 2016 Payment Determination and Subsequent Years

CMS proposes to add one new measure beginning with the FY 2016 payment determination, a yes/no measure of whether the hospital uses a safe surgery checklist during three periods: prior to administration of anesthesia, prior to skin incision and from the closure of incision prior to the patient leaving the operating room. The proposed measure has previously been adopted for use in the hospital outpatient and ambulatory surgical center quality reporting programs. CMS proposes the addition of this measure to the hospital IQR as a means of aligning measures across settings. The measure has not been endorsed by NQF, nor has any other measure assessing use of a safe surgery checklist. CMS believes that the proposed measure reflects consensus because the use of a safe surgery checklist is widely accepted as a best practice for surgical care.

Possible New Quality Measures for Future Years

With respect to possible future measures, CMS emphasizes its expectation that a transition to EHR-based reporting of Hospital IQR Program measures in future years will reduce administrative burden on hospitals of the IQR program. CMS recognizes that much work remains to reach this point including developing electronic

specifications, pilot testing, reliability and validity testing and completing other implementation work.

CMS intends to propose the addition of a smoking cessation measure set and an alcohol cessation measure set developed by The Joint Commission to the Hospital IQR Program once an EHR-based data collection for these measure sets is possible. Each measure set consists of four measures addressing screening, provision or offer of treatment/intervention, steps at discharge and assessing status after discharge. These measure sets were recommended by the MAP for inclusion in the IQR program provided they are NQF-endorsed prior to inclusion. **CMS seeks comments on the potential inclusion of these measure sets.**

As noted earlier, regarding the possible future expansion of data collection on the CLABSI and CAUTI measures beyond the ICU, CMS seeks comment on the feasibility and timing of expanding data collection for acute care hospitals.

In adding measures to the IQR program in the future, CMS intends to support six measurement domains that follow the priorities in the National Quality Strategy: clinical, care coordination, patient safety, experience of care, population/community health, and efficiency.

Form, Manner, and Timing of Quality Data Submission

In general, CMS proposes to retain the data submission requirements for hospitals participating in the Hospital IQR Program, which are codified at 42 CFR 412.140 and further details are available at the QualityNnet.org website. **The proposed changes in the data submission requirements are:**

- **CMS proposes to change the regulations regarding hospitals that are newly participating in (or rejoining) the Hospital IQR Program.** Hospitals joining for a payment determination year would submit a participation form by December 31st of the year prior preceding the 1st quarter of the calendar year for which chart-abstracted data submission is required for that year. For example, for participation in FY 2015, a hospital would need to submit a participation form by December 31, 2012 and submit data beginning with January 1, 2013 discharges.
- **A change is proposed to the regulations regarding withdrawal from the hospital IQR program.** A hospital withdrawing from the IQR program must submit a withdrawal form by May 15th prior to the start of the payment year. For example, to withdraw for FY 2015, the withdrawal form is due by May 15, 2014.
- As noted earlier, data submission for the proposed new chart-abstracted measure on elective delivery prior to 39 completed weeks gestation would be made via a web-based tool. Hospital would submit aggregate numerator, denominator and exclusion counts for this measure. **CMS indicates that the complete details on**

data submission requirements for the proposed new perinatal care measure and deadlines will be posted on the QualityNet website.

- **The proposed timing of data submission for the structural measures** (on registry participation) for the FY 2015 payment determination via the web-based tool is between April 1, 2014 and May 15, 2014 with respect to calendar year 2013.
- **A reporting exception is proposed for hospitals with respect to several of the measures reported through the National Healthcare Safety Network**, specifically the measures on CLABSI, CAUTI and surgical site infection (SSI). Under the process, hospitals without an ICU would not have to report the CLABSI and CAUTI measures, and those with fewer than 10 total combined cases of colon and abdominal hysterectomy procedures in the calendar year prior to the reporting year would not be required to report the SSI measure. A single exception form for this purpose would be provided on the qualitynet.org website.

Supplements to the Chart Validation Process

CMS proposes three modifications to the process that is used to validate data submitted by hospitals with respect to chart-abstracted measures. First, separate validation approaches are proposed for the healthcare associated infection (HAI) measures and the other clinical process of care measures. Second, CMS proposes to reduce the number hospitals included in the annual base validation sample from 800 to 400. Third, CMS proposes to use a targeted selection of supplemental hospitals to be added to the base sample.

Validation of HAI measures. **CMS proposes a separate process for validation of the HAI measures,** which are reported differently from other chart abstracted measures (through the NHSN) and which involve relatively rare events. This would involve the CLABSI, CAUTI and SSI measures. The latter two measures were added to the Hospital IQR Program beginning with the FY 2014 payment determination year and no data validation approach has yet been proposed for them. The approach finalized in last year's rule for validation of the CLABSI measure by abstracting CLABSI data from the records selected for other chart-abstracted measures would be discontinued in favor of the new proposed approach for all HAI measures. The only change proposed to the previously finalized process for validation of other chart-abstracted measures is to discontinue the policy of abstracting emergency department and immunization cases from CLABSI records. CMS proposes this change in light of the other changes involving validation of the HAI measures.

Under the proposed new process for validation of the HAI measures, CMS would construct a list of candidate events for each of the three measures, and then create a combined list of candidate HAI events which would be used to generate a random sample of medical records for evaluation of the presence or absence of one or more of the HAI events. In combining the three lists, CMS would remove duplicates for a given

episode of care. The proposed rule describes the process for developing the three candidate event lists.

- For CLABSI, CMS would modify the approach that was finalized in last year's rulemaking that requires sampled hospitals to submit to CMS a listing of positive blood cultures drawn from ICU patients, with an annotation to indicate whether the patient had a central venous catheter. The proposed modification would require that the Medicare health insurance claim number (if there is one) be added to the positive blood culture list. This would allow matching of the candidate event lists for CLABSI with those for SSI, which will be identified through claims data. For data privacy, CMS proposes that the positive blood culture lists be submitted through the secure data exchange on the QualityNet.org website.
- A process similar to that for CLABSI would be adapted for CAUTI. Hospitals targeted for validation would be asked to submit a list of positive urine cultures among ICU patients adding the Medicare claim number when there is one. A CMS contractor would review the list to eliminate urine cultures not consistent with an ICU-associated CAUTI and to reduce the list to one entry per ICU patient.
- For SSI, CMS proposes a different process from the other two measures because SSIs are reported more frequently in claims data. Claims for Medicare patients who had colon or abdominal hysterectomy surgery would be reviewed including the index admission and readmissions within 30 days to the index hospital to identify discharge diagnoses that indicate infection. CMS indicates that details of the approach are in an article by Richard Platt and others published in the December 2002 edition of *Emerging Infectious Diseases* which may be accessed online at http://cdc.gov/eid/content/8/12/pdfs/v8-n12.pdf. In discussing this approach, CMS acknowledges limitations of excluding readmissions to other hospitals, and notes that the current regulations require hospitals to maintain medical records that document HAI but there is no requirement to document whether follow-up was performed. CMS seeks comments on how to fill the gap in SSI validation in the future.

Once the combined unduplicated list was created, a random sample of 12 candidate events per quarter would be drawn, or a total of 48 events per year. CMS states that this sample size would be sufficient to estimate a passing validation score (75%) with a margin of error of plus or minus 10 points with 90% confidence for hospitals that have as many as 480 candidate events in a year, a level that is higher than what CMS believes most hospitals experience. CMS proposes that in a quarter where a hospital has fewer than 12 candidate events, all candidates would be selected for validation.

CMS proposes to separately score validation of the HAI measures, noting that because these are rare events if the scoring was combined with other chart-abstracted measures a hospital could incorrectly report all HAI targeted records and still obtain a 75% overall validation score. Under the proposal, hospitals would need to receive a passing

score on both the HAI and chart-abstracted clinical process of care measures to pass validation for the FY 2014 payment determination and subsequent years.

Scoring for the HAI measures would follow the process previously finalized for the CLABSI measure. If a record includes one event that was reported to NHSN, a full score would be awarded for that record. If a record includes multiple events (e.g., CLABSI and CAUTI), both events would have had to have been reported to NHSN to receive a full score for validation. If a record includes no events and none were reported, a full scored would be awarded. No points would be awarded if the wrong infection was reported or if an infection was reported and the validation data does not support the event.

CMS proposes that in requesting medical records for SSI that is identified based on a readmission diagnosis, hospitals would be asked to provide the record for the initial hospitalization as well as the readmission. For CLABSI and CAUTI only the index hospital stay record would be reviewed.

A mean HAI score would be computed as the number of HAI records correctly classified divided by the total number of HAI records scored, with a variance calculated in all cases except where the validation sample includes all the hospital's HAI events for the year. CMS proposes that the standard for a passing score would be modified to require a 75% score for both the clinical process of care and HAI measures (unless the HAI measures are not applicable because there were no events or the hospital was excepted from NHSN reporting), and that each of these scores would be computed over the four quarters rather than for each quarter. Further, CMS proposes that a two-tailed 90 percent confidence interval replace the current standard of a one-tailed 95 percent confidence interval. This is in response to a GAO report that found a large number of hospitals for which the statistical margin of error included both passing and failing scores.

Reduced Base Sample Size and Targeted Sampling. **CMS proposes to reduce from 800 to 400 the annual random sample of hospitals for validation because a very high percentage of hospitals pass validation.** As under current policy, any IQR-program eligible hospital submitting at least one IQR case during the third quarter of calendar year 2012 would be eligible for selection in the random sample, which would occur in early 2013 for the FY 2015 payment determination.

CMS proposes to discontinue its policy of including in the validation sample all hospitals that have not been selected in the previous three years. CMS estimates that this could create a supplemental sample size as high as 1,300 hospitals for the FY 2015 payment determination. Instead, **CMS proposes that in addition to the base random sample of 400 hospitals, up to 200 additional hospitals will be selected for validation based on targeted criteria.** CMS would continue its policy of including in the validation sample all hospitals that failed validation in the previous year. Then, a random sample of hospitals meeting other targeting criteria would be chosen up to a total of 200 hospitals in the supplemental validation group. One criteria would be

whether the hospital was not selected as part of the base random sample for the previous 3 years. The other criteria for selecting additional hospitals for validation would be hospitals with abnormal or conflicting data patterns, rapidly changing data patterns, hospitals submitting data to the NHSN after the IQR deadline has passed, and hospitals that joined the IQR program within the past 3 years and have not been selected for validation. Beginning with the FY 2016 payment determination, CMS proposes to add to the list of targeted criteria hospitals that passed validation in the previous year but, under the new proposed scoring, had a two-tailed confidence interval that included 75 percent.

Other Provisions

For participation in the Hospital IQR Program for the FY 2015 payment determination, hospitals would need to submit the electronic Data Accuracy and Completeness Acknowledgement by May 15, 2014 with respect to calendar year 2013 reporting.

No changes are proposed with respect to requirements and procedures for public display of Hospital IQR Program measures, reconsiderations and appeals, and disaster extensions or waivers.

The preamble includes a discussion of the relationship between the Hospital IQR Program and the Medicare payment incentives for the use of EHR technology provided under the HITECH Act. CMS reiterates its goal of aligning the two program requirements, noting that not all IQR program measures, such as HCAHPS, lend themselves to electronic reporting.

Hospital IQR Program Measures for Payment Determinations for FYs 2014, 2015 and 2016 (* Indicates Measure Proposed in this Rule)			
	2014	**2015**	**2016**
Acute Myocardial Infarction (AMI) Measures			
AMI-2 Aspirin prescribed at discharge	X	X	X
AMI-7a Fibrinolytic (thrombolytic) agent received within 30 minutes of hospital arrival	X	X	X
AMI-8a Timing of Receipt of Primary Percutaneous Coronary Intervention (PCI)	X	X	X
AMI-10 Statin Prescribed at Discharge	X	X	X
Heart Failure (HF) Measures			
HF-1 Discharge instructions	X	X	X
HF-2 Evaluation of left ventricular systolic function	X	X	X
HF-3 Angiotensin Converting Enzyme Inhibitor (ACE-I) or Angiotensin II Receptor Blocker (ARB) for left ventricular systolic dysfunction	X	X	X
Stroke (STK) Measure Set			
STK-1 VTE prophylaxis		X	X
STK-2 Antithrombotic therapy for ischemic stroke		X	X
STK-3 Anticoagulation therapy for Afib/flutter		X	X
STK-4 Thrombolytic therapy for acute ischemic stroke		X	X

Hospital IQR Program Measures for Payment Determinations for FYs 2014, 2015 and 2016 (* Indicates Measure Proposed in this Rule)			
	2014	**2015**	**2016**
STK-5 Antithrombotic therapy by the end of hospital day 2		X	X
STK-6 Discharged on Statin		X	X
STK-8 Stroke education		X	X
STK-10 Assessed for rehabilitation services		X	X
Venous Thromboembolism (VTE) Measure Set			
VTE-1 VTE prophylaxis		X	X
VTE-2 ICU VTE prophylaxis		X	X
VTE-3 VTE patients with anticoagulation overlap therapy		X	X
VTE-4 VTE patients receiving un-fractionated Heparin with doses/labs monitored by protocol		X	X
VTE-5 VTE discharge instructions		X	X
VTE-6 Incidence of potentially preventable VTE		X	X
Pneumonia (PN) Measures			
PN-3b Blood culture performed before first antibiotic received in hospital	X	X	X
PN-6 Appropriate initial antibiotic selection	X	X	X
Surgical Care Improvement Project (SCIP) Measures			
SCIP INF-1 Prophylactic antibiotic received within 1 hour prior to surgical incision	X	X	X
SCIP-INF-2: Prophylactic antibiotic selection for surgical patients	X	X	X
SCIP-INF 3 Prophylactic antibiotics discontinued within 24 hours after surgery end time (48 hours for cardiac surgery)	X	X	X
SCIP-INF-4: Cardiac surgery patients with controlled 6AM postoperative serum glucose	X	X	X
SCIP–INF-9: Postoperative urinary catheter removal on post operative day 1 or 2 with day of surgery being day zero	X	X	X
SCIP-INF-10: Surgery patients with perioperative temperature management	X	X	X
SCIP-Cardiovascular-2: Surgery Patients on a Beta Blocker prior to arrival who received a Beta Blocker during the perioperative period	X	X	X
SCIP-VTE-1: Surgery patients with Venous thromboembolism (VTE) prophylaxis ordered	X	Removal*	Removal*
SCIP-VTE-2: Surgery patients who received appropriate VTE prophylaxis within 24 hours pre/post surgery	X	X	X
Mortality Measures (Medicare Patients)			
AMI 30-day mortality rate	X	X	X
Heart Failure 30-day mortality rate	X	X	X
Pneumonia 30-day mortality rate	X	X	X
Patients' Experience of Care Measures			
HCAHPS survey	X	X	Additions Proposed*[1]
Readmission Measures (Medicare Patients)			
AMI 30-Day Risk Standardized Readmission	X	X	X
Heart Failure 30-Day Risk Standardized Readmission	X	X	X

Hospital IQR Program Measures for Payment Determinations for FYs 2014, 2015 and 2016 (* Indicates Measure Proposed in this Rule)			
	2014	**2015**	**2016**
Pneumonia 30-Day Risk Standardized Readmission	X	X	X
30-Day Risk Standardized Readmission following Total Hip/Total Knee Arthroplasty		X*	X*
Hospital-wide all cause unplanned readmission		X*	X*
AHRQ Patient Safety Indicators (PSIs), Inpatient Quality Indicators (IQIs) and Composite Measures			
PSI 06: Iatrogenic pneumothorax, adult	X	Removal*	Removal*
PSI 11: Post Operative Respiratory Failure	X	Removal*	Removal*
PSI 12: Post Operative PE or DVT	X	Removal*	Removal*
PSI 14: Postoperative wound dehiscence	X	Removal*	Removal*
PSI 15: Accidental puncture or laceration	X	Removal*	Removal*
IQI 11: Abdominal aortic aneurysm (AAA) mortality rate (with or without volume)	X	Removal*	Removal*
IQI 19: Hip fracture mortality rate	X	Removal*	Removal*
Complication/patient safety for selected indicators (composite)	X	X	X
Mortality for selected medical conditions (composite)	X	Removal*	Removal*
PSI 04 Death among surgical inpatients with serious, treatable complications	X	X	X
Structural Measures			
Participation in a Systematic Database for Cardiac Surgery	X	X	X
Participation in a Systematic Clinical Database Registry for Stroke Care	X	X	X
Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care	X	X	X
Participation in a Systematic Clinical Database Registry for General Surgery	X	X	X
Safe Surgery Checklist Use			X*
Healthcare-Associated Infections Measures			
Central Line Associated Bloodstream Infection	X	X	X
Surgical Site Infection	X	X	X
Catheter-Associated Urinary Tract Infection	X	X	X
MRSA Bacteremia		X	X
Clostridium Difficile (C.Diff)		X	X
Healthcare Personnel Influenza Vaccination		X	X
Surgical Complications			
Hip/Knee Complication: Hospital-Level Risk Standardized Complication Rate (RSCR) following Elective Primary Total Hip Arthroplasty		X*	X*
Hospital Acquired Condition (HAC) Measures			
Foreign Object Retained After Surgery	X	Removal*	Removal*
Air Embolism	X	Removal*	Removal*
Blood Incompatibility	X	Removal*	Removal*
Pressure Ulcer Stages III & IV	X	Removal*	Removal*

Hospital IQR Program Measures for Payment Determinations for FYs 2014, 2015 and 2016 (* Indicates Measure Proposed in this Rule)			
	2014	**2015**	**2016**
Falls and Trauma (Includes: Fracture, Dislocation, Intracranial Injury, Crushing Injury, Burn, Electric Shock)	X	Removal*	Removal*
Vascular Catheter-Associated Infection	X	Removal*	Removal*
Catheter-Associated Urinary Tract Infection (UTI)	X	Removal*	Removal*
Manifestations of Poor Glycemic Control	X	Removal*	Removal*
Emergency Department (ED) Throughput Measures			
ED-1 Median time from ED arrival to departure from the emergency room for patients admitted to the hospital	X	X	X
ED-2 – Median time from admit decision to time of departure from the ED for ED patients admitted to the inpatient status	X	X	X
Prevention			
Global Flu Immunization	X	X	X
Global Pneumonia Immunization	X	X	X
Cost Efficiency			
Medicare Spending per Beneficiary	X	X	X
Perinatal Care			
Elective delivery < 39 completed weeks gestation		X*	X*

[1]Questions related to care transitions, mental health status and admission through the ED are proposed for addition to the HCAHPS.

B. Proposed PPS-Exempt Cancer Hospital Quality Reporting Program

This section of the rule establishes a quality reporting program beginning in FY 2014 for PPS-exempt cancer hospitals (PCHs) as required under section 3005 of the ACA. As proposed, the PPS-exempt Cancer Hospital Quality Reporting (PCHQR) program would follow many of the policies established for the Hospital IQR Program, including the principles for selecting measures and the procedures for hospital participation in the program. CMS also took into account the views of participants in a September 2011 listening session and input from a PCH technical expert panel convened by a CMS contractor which rated potential measures for this program.

CMS proposes five measures for the new cancer hospital quality reporting program to begin in FY 2014. All five measures have been endorsed by the NQF and recommended for inclusion in the program by the MAP. Two measures (CLABSI and CAUTI) are healthcare associated infection measures that are already adopted for the Hospital IQR Program and other quality reporting programs. The other three measures are process of care measures specific to cancer that were developed by the American College of Surgeons/Commission on Cancer accreditation program, and are reported by more than 1,500 cancer programs. The five proposed measures are:

1. NHSN CLABSI outcome measure
2. NHSN CAUTI outcome measure

3. Adjuvant chemotherapy is considered or administered with 4 months (120 days) of surgery to patients < 80 with AJCC T1c (lymph node positive) colon cancer (NQF #0223)
4. Combination chemotherapy is considered or administered within 4 months (120 days) of diagnosis to women < 70 with AJCC T1c or Stage II or III hormone receptor negative breast cancer. (NQF #0559)
5. Adjuvant hormonal therapy (NQF #0220) (Tamoxifen or third generation aromatase inhibitor is considered or administered within 1 year of diagnosis to women > 18 with AJCC T1cN0M0, or Stage II or III hormone receptor positive breast cancer.)

The NHSN CLABSI and CAUTI measures would apply to both ICU and non-ICU locations in a PPS-exempt cancer hospital. As noted earlier, for the Hospital IQR Program, CMS proposes to continue to apply this measure only for ICU locations, which was how it was originally specified. PCHs would report these measures through the NHSN. In discussing the application of these measures to PCHs, CMS notes that the PCH technical expert panel identified CLABSI and CAUTI as high priority quality issues for PCHs.

CMS proposes that data on the three proposed cancer-specific measures would be reported by PCHs to a CMS contractor. In discussing the rationale for the three proposed cancer-specific measures, CMS reports that not only are colon and breast cancer prevalent among Medicare beneficiaries, the PCH technical expert panel gave the proposed measures the highest rating among the potential measures. Specifications for the three cancer-specific measures are available at http://facs.org/cancer/ncdb/colonmeasures.pdf and http://facs.org/cancer/ncdb/breastmeasures.pdf.

CMS welcomes comments on possible future measures for the PCH quality reporting program, indicating that it will consider measures in six domains that flow from the National Quality Strategy priorities: clinical quality of care, care coordination, patient safety, patient and caregiver experience of care, population/community health and efficiency.

The proposed rule sets forth procedures that would be required for PCHs to participate in the quality reporting program. These parallel the procedures in place for the Hospital IQR Program. PCHs would register with the QualityNet.org website, which would be used to make available the information that PCHs need to participate in the program, including measure specifications and instructions for data submission. For PCHs that file a notice of participation, performance on the measures would be posted on the *Hospital Compare* website and PCHs would have 30 days to review the data before it is posted. PCHs would be required to electronically submit an annual data accuracy and completeness acknowledgment.

Data submission deadlines are proposed. The initial data submission deadlines PCHs proposed would require PCHs to begin submitting quarterly data through the NHSN on

the CLABSI and CAUTI measures by May 15, 2013 for infections occurring during the quarter beginning on October 1, 2012. For applicable cancer cases with an initial diagnosis during the fourth quarter of calendar year 2012, data submission would be required by August 15, 2013 for two of the process of care cancer measures and by May 15, 2014 for the adjuvant hormonal therapy measure.

With respect to measure maintenance, CMS makes the same proposal as described earlier for the Hospital IQR Program. That is, NQF updates to program measure specifications that CMS believes do not substantially change the measure would be incorporated into the program through a subregulatory process.

C. Hospital Value-Based Purchasing (VBP) Program

1. Overview

FY 2013 is the first year of payment adjustments under the hospital VBP program established by the ACA. CMS will base each hospital's VBP percentage on its Total Performance Score (TPS) for a specified performance period. The total amount available for value-based incentive payments for a fiscal year is equal to the total amount of the payment reductions for all participating hospitals for such fiscal year, as estimated by the Secretary. For FY 2013, the available funding pool equals 1.00 percent of the base-operating DRG payments to all participating hospitals, as estimated by the Secretary; the funding pool increases to 1.25 percent of base-operating DRG payments for FY 2014, 1.50 percent for FY 2015, 1.75 percent for FY 2016, and 2.0 percent for FY 2017 and successive fiscal years.

The VBP program includes all subsection (d) hospitals (i.e., IPPS hospitals), with three exclusions with respect to a particular fiscal year: (1) a hospital that is subject to the Hospital IQR payment reduction under section 1886(b)(3)(B)(viii)(I) for the fiscal year; (2) a hospital for which, during the performance period for the fiscal year, the Secretary has cited deficiencies that pose immediate jeopardy to the health or safety of patients; and (3) a hospital for which there are not a minimum number (as determined by the Secretary) of measures that apply to the hospital for the performance period for the fiscal year involved, or for which there are not a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for the fiscal year.

CMS published a final rule in April 2011 (76 FR 26490 through 26547) establishing the VBP program and setting program requirements for the FY 2013 Hospital VBP Program. The final rule adopted 13 measures, including 12 clinical process of care measures and 8 dimensions from the Hospital Consumer Assessment of Healthcare Providers and Systems Survey (HCAHPS), and categorized them into two domains: a clinical process of care domain with 12 clinical process of care measures and a patient experience of care domain with the HCAHPS survey measure. CMS adopted a 3-quarter performance period from July 1, 2011 through March 31, 2012 for the measures, and performance standards for evaluating hospital performance. To

determine whether a hospital meets or exceeds the performance standards for these measures, CMS will assess each hospital's achievement during the performance period, as well as its improvement during this period compared to its performance during a 3-quarter baseline period from July 1, 2009 through March 31, 2010.

CMS will calculate a TPS for each hospital by summing the greater of the hospital's achievement or improvement points for each measure to determine a score for each domain, weighting each domain score (for the FY 2013 Hospital VBP Program, the weights are 70 percent for clinical process of care and 30 percent for patient experience of care), and adding together the weighted domain scores. CMS will convert each hospital's TPS into a value-based incentive payment percentage using a linear exchange function.

2. FY 2014 Hospital VBP Measures

CMS adopted 17 measures for the Hospital VBP Program for FY 2014, including the 12 clinical process of care measures and the HCAHPS measure that were adopted for the FY 2013 program. The FY 2014 VBP measures include:

- 1 new clinical process of care measure (SCIP-Inf-9: Postoperative Urinary Catheter Removal on Postoperative Day 1 or 2), and
- 3 mortality outcome measures (Acute Myocardial Infarction (AMI) 30-Day Mortality Rate, Heart Failure (HF) 30-Day Mortality Rate, Pneumonia (PN) 30-Day Mortality Rate).

The clinical process of care, HCAHPS, and mortality measures are discussed in more detail in the Hospital Inpatient VBP Program final rule (76 FR 26510 through 26511) and SCIP-Inf-9 is discussed in more detail in the CY 2012 OPPS/ASC final rule (76 FR 74530).

In the CY 2012 OPPS/ASC final rule, CMS suspended the effective date of several other measures that it had adopted for the FY 2014 program: 8 HAC measures, 2 AHRQ composite measures, and a Medicare Spending per Beneficiary Measure; these measures are not included in the FY 2014 Hospital VBP Program (76 FR 74528 through 74530). The table on pages 94-95 provides a complete list of the measures adopted for the FY 2014 Hospital VBP Program as well as the measures proposed for the FY 2015 program.

3. Other Previously Finalized Requirements for the Hospital VBP Program

In the CY 2012 OPPS/ASC final rule (76 FR 74532 through 74547), CMS finalized a number of other policies for the FY 2014 Hospital VBP Program including: the minimum number of cases that a hospital must report to receive a score on a mortality measure; the minimum number of measures that a hospital must report in order to receive a score on the outcome domain; the baseline and performance periods; the performance standards for the clinical process of care and patient experience of care measures (CMS had previously finalized the performance standards for the 3 mortality outcome measures in the Hospital Inpatient VBP Program final rule (76 FR 26513));

the scoring methodology; and the domain weighting methodology. CMS also finalized for all years of the program a process whereby hospitals may review and correct the data that they submit to the QIO Clinical Warehouse on clinical process of care measures, their clinical process of care measure rates, their HCAHPS data, and their patient-mix and mode adjusted HCAHPS scores.

4. Proposed Hospital VBP Payment Adjustment Calculation Methodology

For purposes of the Hospital VBP Program, CMS defines the term "base operating DRG payment amount" as the wage-adjusted DRG operating payment plus any applicable new technology add-on payment. This definition follows the one proposed in this rule for the Hospital Readmissions Reduction Program. The definition excludes adjustments for IME, DSH, low-volume hospitals, outliers and the readmissions reduction program adjustment. In addition to the wage adjustment, it includes the COLA adjustments for Alaska and Hawaii. For SCHs that receive payments based on their hospital-specific payment rate, the base operating DRG payment amount excludes the difference between the hospital's applicable hospital-specific payment rate and the Federal payment rate. (A similar policy applies to MDHs prior to the scheduled termination of that program effective October 1, 2012.) For Maryland waiver hospitals paid under section 1814(b)(3), CMS proposes to define the term "base operating DRG payment amount" to be the payment amount under that section, as provided by section 1886(o)(7)(D)(ii)(II) of the Act. CMS invites comment on these proposals.

To create the funding pool for value-based incentive payments for each fiscal year, CMS proposes that beginning with FY 2013 discharges, every hospital eligible for the VBP program would have its base operating DRG payment amount reduced by the "applicable percent" for each discharge in a fiscal year, regardless of whether CMS has determined that the hospital has earned a value-based incentive payment for that fiscal year. The applicable percent is 1.0 percent in FY 2013, increasing gradually to 2.0 percent in FY 2017. The total amount of reductions over all hospitals would constitute the pool from which CMS would make VBP incentive payments. CMS proposes to determine these amounts from MedPAR data in December of the previous fiscal year for development of preliminary estimates for the annual proposed rule and in March for the final rule estimates. Using FY 2011 MedPAR data inflated to FY 2013 dollars, CMS estimates the available amount for FY 2013 value-based incentive payments to be $956 million.

Beginning with the FY 2014 Hospital VBP Program, CMS will make the value-based incentive payments to hospitals as part of the claims payment process, beginning at the start of the fiscal year. CMS will notify hospitals of the net result of the base operating DRG payment amount reduction and the value-based incentive payment adjustment no later than 60 days prior to the start of the fiscal year, as required by the statute.

The "value-based incentive payment percentage" is the percentage of the total base operating DRG payment amount that a hospital has earned back, based on its TPS for a fiscal year. CMS will calculate a value-based incentive payment percentage for each

hospital that receives a TPS greater than zero with respect to a fiscal year. A hospital may earn a value-based incentive payment percentage that is less than, equal to, or more than the applicable percent.

CMS will use the linear exchange function that it finalized in the Hospital Inpatient VBP Program final rule (76 FR 26534) to convert each hospital's TPS into a value-based incentive payment factor to be applied to each discharge in the fiscal year. A hospital with no net percentage change to its total base operating DRG payment amount percentage would have a value-based incentive payment adjustment factor of one: its base operating DRG payment amount for each discharge is multiplied by 1 so that its base-operating DRG payment amount would be equal to what it would have been in the absence of the Hospital VBP Program. A hospital with a negative net percentage change to its total base-operating DRG payment amount percentage would have a value-based incentive payment adjustment factor that is less than one and a hospital with a positive net percentage change would have a value-based incentive payment adjustment factor that is greater than one. CMS welcomes comments.

Proposed Timing of the Base Operating DRG Payment Amount Reduction and Value-Based Incentive Payment Amount Adjustment. In the Hospital Inpatient VBP Program final rule (76 FR 26536), CMS stated that it would incorporate the value-based incentive payment adjustment into the claims processing system in January 2013, and that the adjustment would apply to all FY 2013 discharges, including those occurring in the first quarter of the fiscal year. CMS proposes to delay application of the 1.00 percent applicable reduction to the base operating DRG payment amount until it applies the value-based incentive payment adjustment factor. Beginning in January 2013, a hospital would receive a base operating DRG payment amount for each discharge occurring in FY 2013 that is the net result of the application of the 1.00 percent reduction and the application of the hospital's individual value-based incentive payment amount adjustment. In FY 2014 and future years, these adjustments would begin on October 1.

For FY 2013, CMS proposes to reprocess claims submitted prior to January 2013, which is when it currently expects to incorporate the VBP adjustments into the claims processing system. Although hospitals would not be required to resubmit claims, CMS recognizes the burden which reprocessing places on hospitals for tracking and accounting of these claims. The proposed rule describes and invites comment on an alternative approach that would modify the slope of the exchange function as necessary so that it could be used to calculate a value-based incentive payment adjustment for each hospital such that the equivalent of the full fiscal year effect is achieved between January and September 30, 2013. Employing the alternative approach would require accepting the assumption that hospitals' base operating DRG payments are constant over the course of the fiscal year (that is, DRG payments are not concentrated in the beginning or the end of the year, for example). CMS solicits comments on the two approaches.

5. Review and Corrections Process

CMS proposes to implement a process by which hospitals would have the opportunity for confidential review and correction of the claims-based measure rates and scores calculated by CMS in developing the VBP total performance score. For claims-based measure calculations, CMS would create data extracts of claims 90 days after the end of the performance period to be used in calculating measure rates. Hospitals would be provided with a confidential report containing the measure rates calculated and relevant discharge-level details for review. Similar to the process used to allow hospitals review of IQR program data prior to its public release, these reports would be made available to hospitals through its secure QualityNet account, and hospitals would have 30 days to review the information and submit corrections. If CMS agrees that a correction is needed a new confidential report would be prepared for the hospital. Hospitals would not be able to submit corrections to the claims data that was originally submitted and could not submit additional claims data for the performance period. CMS points out that given the time required for CMS to calculate the rates, extending the capture date past 90 days would delay the timing of when hospitals could review the CMS calculations from 18 to 24 months after the end of the performance period.

Separate from the claims-based measures calculation report, CMS proposes to provide hospitals, via their QualityNet account, with a confidential Total Performance Score (TPS) Report that includes the hospital's score for each condition, domain scores, and the TPS. Hospitals would have 30 days to review these scores and submit corrections. Submitting a correction on a score would be a prerequisite to appealing the score, which is discussed below. CMS does not propose to use this corrections process to reconsider whether a hospital is eligible to participate in the VBP program for a year, but seeks public comment on whether that would be an appropriate use of the corrections process.

6. Appeal Process

The ACA requires the Secretary to establish a process for a hospital to appeal the calculation of the hospital's performance related to the performance standards or the calculation of the total performance score. Other elements of the VBP program are specifically excluded in the statute from administrative or judicial review. These include the calculation of the VBP payment amounts, the total amount available for distribution, and the methodology for calculating the performance score.

CMS proposes that a hospital that has requested a correction to a score for a measure, dimension, or total score under the proposed review and correction process and that request was rejected, an appeal could be sought through the QualityNet website within 30 days after receipt of the rejection. Appeals on other matters could be submitted within 30 days after the corrections period ends. The proposed rule identifies the following specific items as those for which a hospital could submit an appeal:

- CMS' decision to deny a hospital's correction request that the hospital submitted under the review and corrections process;
- Whether the achievement/improvement points were calculated correctly;
- Whether CMS properly used the higher of the achievement/improvement points in calculating the hospital's measure/dimension score;
- Whether CMS correctly calculated the domain scores, including the normalization calculation;
- Whether CMS used the proper lowest dimension score in calculating the hospital's HCAHPS consistency points;
- Whether CMS calculated the HCAHPS consistency points correctly;
- Whether the correct domain scores were used to calculate the TPS;
- Whether each domain was weighted properly;
- Whether the weighted domain scores were properly summed to arrive at the TPS; and,
- Whether the hospital's open/closed status (including mergers and acquisitions) is properly specified in CMS' systems.

7. Measures for the FY 2015 Hospital VBP Program

For FY 2015, CMS proposes to retain 14 of the 15 measures adopted for the FY 2014 VBP program and to add four additional measures. The measure adopted for FY 2014 that would be dropped is SCIP-VTE-1: Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered. As discussed earlier in this summary, CMS is proposing to remove this measure from the Hospital IQR Program in FY 2015. The four new measures include one clinical process of care measure, two outcome measures, and an efficiency measure. One of the proposed outcome measures (AHRQ composite measure) and the efficiency measure were both adopted for the FY 2014 VBP in previous rulemaking but subsequently withdrawn because the requirement that hospital performance on the measures be posted on the *Hospital Compare* website for one year prior to the start of the performance year had not been met.

The four measures proposed for addition are shown in the table below, along with the dates that the proposed rule indicates are when performance data on these measures were first posted on the *Hospital Compare* website. CMS indicates that although the efficiency measure had not been posted on *Hospital Compare* at the time the proposed rule was released, posting was expected to occur by the end of April 2012, and the proposed performance period for this measure would begin on May 1, 2013.

Proposed Measure	**Domain**	**Date first posted on Hospital Compare**
AMI-10: Statin Prescribed at Discharge	Clinical process of care	January 26, 2012
PSI-90, AHRQ patient safety composite	Outcome	October 14, 2011
CLABSI	Outcome	January 26, 2012

Medicare spending per beneficiary	Efficiency	Mid to late April 2012

CMS notes that one IQR program measure that was a candidate for addition to the VBP program was not chosen for addition because it is "topped out". That measure is SCIP-Inf-10: Surgery Patients with Perioperative Temperature Management.

CMS proposes to generally continue measures that were previously adopted for the VBP program. Measures would be proposed for removal if they are topped out or for other reasons, and these changes would be subject to rulemaking.

A summary table showing the VBP measures previously adopted for FY 2014 and those proposed in this rule for FY 2015 are included at the end of this section.

8. Measures and Domains for FY 2016

CMS proposes to continue for the FY 2016 VBP program the previously adopted 30-day mortality measures for heart attack, heart failure and pneumonia, and the proposed AHRQ composite patient safety measure. No other measures are proposed for FY 2016, although if the earlier proposal to regularly retain previous VBP program measures is finalized, all the FY 2015 measures would be continued into FY 2016 unless they were proposed for removal. CMS indicates that adopting these measures now would permit a longer performance period. Specifically, CMS proposes that the performance period for these measures for the FY 2016 VBP program would begin on October 1, 2012. CMS expects to propose additional measures for FY 2016 in future rulemaking.

A revised domain structure is proposed for the VBP program beginning in FY 2016. In place of the current four domains (Clinical Process of Care, Patient Experience of Care, Outcomes and Efficiency), CMS proposes to employ six domains that reflect the National Quality Strategy priorities. These are: Clinical Care; Person- and Caregiver-Centered Experience and Outcomes; Safety; Efficiency and Cost Reduction; Care Coordination; and Community/ Population Health.

The proposed rule includes a table that illustrates how the FY 2015 measure set would translate into the proposed new six-domain structure. All but one of the measures in the current clinical process of care domain would be placed in the new clinical care domain, HCAHPS would continue under experience of care, and Medicare spending per beneficiary would continue under efficiency. The measures changing categories are:

- 'HF-1: Discharge instructions' would shift from Clinical Process of Care to the new Care Coordination domain
- The three 30-day mortality measures (for heart attack, heart failure, and pneumonia) would shift from the Outcomes domain to Clinical Care
- CLABSI and the AHRQ composite patient safety measures would move from the Outcomes domain to the new Patient Safety domain

In discussing the new proposed domains, CMS acknowledges that some measures could arguably be placed in more than one domain, and therefore the chosen domain should reflect the primary purpose of the measure. CLABSI is offered as an example of a measure that might be a clinical process of care measure but is better captured as a patient safety measure. **CMS specifically seeks comments on including both clinical process of care and outcome measures in the new clinical care domain and asks whether the current approach that groups all outcome measures as a single domain should be continued.**

VBP scoring would continue to be calculated by aggregating measures within a domain and weighting the domains. **CMS seeks comments on the weighting of the proposed six-domain structure.** No weights are proposed, but CMS indicates that the weights should reflect the most critical needs for quality improvement and should also take into account the relative depth and maturity of the measures included in the domain. A domain with measures that do not capture sufficient aspects of care would be given a relatively low weight. CMS expects that weighting will change over time as the measure set evolves.

9. Performance Periods and Baseline Periods for FY 2015 and 2016

The proposed baseline and performance periods for FY 2015 are shown in the table below. For FY 2015, CMS states that a performance period of 9 months is the longest one possible for the mortality data given the time constraints that result from the requirement for publishing performance standards at least 60 days prior to the start of the performance period. **CMS is particularly interested in comments on the proposed baseline and performance periods for the mortality and AHRQ composite measures for FY 2016.** CMS is proposing a 21-month performance period, beginning on October 1, 2012. The baseline period would be the same nine-month period used for FY 2015. In making this proposal, CMS is seeking to have a longer performance period and to calculate the performance standard using the most recent possible data. CMS seeks to establish a 24-month performance period for future years, but notes the constraints that result from the requirement that performance standards be published at least 60 days prior to the start of the performance period.

In light of the timing constraints imposed by using the annual IPPS and OPPS rulemaking cycle for updating VBP program elements, CMS proposes to update performance periods and performance standards outside the rulemaking process using methodologies finalized during rulemaking. The periods and standards would be posted in a notice on the CMS website or other public website.

Domain/Measures	Baseline Period	Performance Period
FY 2015		
Clinical Process of Care		
AMI-10	April 1, 2011 – Dec. 31, 2011	April 1 – Dec. 31, 2013

Domain/Measures	Baseline Period	Performance Period
All other	January 1, 2011 – Dec. 31, 2011	Jan. 1, 2011 – Dec. 31, 2013
Patient Experience of Care		
HCAHPS	January 1, 2011 – Dec. 31, 2011	January 1 – Dec. 31, 2013
Outcomes		
Mortality	October 1, 2010 – June 30, 2011	Oct. 1 2012 – June 30, 2013
AHRQ composite	Oct. 15, 2010 – June 30, 2011	Oct. 15 2012 – June 30, 2013
CLABSI	Jan. 26, 2011 – Dec. 31, 2011	Jan. 26, 2013 – Dec. 31, 2013
Efficiency		
Medicare spending per beneficiary	May 1, 2011 – Dec. 31, 2011	May 1, 2013 – Dec. 31, 2013
FY 2016		
Outcomes		
Mortality	Oct. 1, 2010 – June 30, 2011	Oct. 1, 2012 – June 30, 2014
AHRQ composite	Oct. 1, 2010 – June 30, 2011	Oct. 1, 2012 – June 30, 2014

10. Performance Standards for FY 2015 and FY 2016

The proposed rule includes tables showing the estimated performance standards for all proposed measures for FY 2015 and FY 2016, which CMS has calculated using the methodology finalized in previous VBP rulemaking. The calculations will be updated for the final rule. The tables are not reproduced in this summary.

The discussion in the proposed rule notes that the future transition to ICD-10-CM/PCS coding will result at some point in time in performance standards calculated in a period during which ICD-9-CM/PCS coding was used, and **CMS seeks comments on how to fairly compare hospital performance that is captured using different coding sets.**

As noted earlier, CMS proposes to update performance period and performance standards outside the rulemaking process using methodologies finalized in rulemaking. The periods and standards would be posted in a notice on the CMS website or other public website.

11. FY 2015 VBP Program Scoring Methodology

CMS proposes to continue for FY 2015 the previously finalized VBP scoring methodology without change.

Proposed domain weights for FY 2015, reflecting the addition of the Efficiency domain are shown in the table below, with FY 2013 and FY 2014 weighting shown for comparison purposes.

	VBP Program Weighting (Fiscal Year)		
Domain	**2013**	**2014**	**2015—Proposed**
Clinical process of care	70%	45%	20%
Patient experience of care	30%	30%	30%
Outcomes		25%	30%
Efficiency			20%

CMS proposes to change the minimum number of domains for which a hospital must have a score in order to receive a total performance score under the hospital VBP program. Specifically, CMS proposes that for FY 2015, hospitals must have scores for at least two domains in order to receive a total score for the VBP program. Scores would be reweighed so that the total possible points would always be 100 and the relationship between the domains would be consistent. Currently, hospitals must have a score for each domain (i.e., all three domains for FY 2014), and specific requirements apply to the minimum number of cases and measures that a hospital must have in order to receive a score for a domain. As discussed below, CMS proposes to increase the number of cases that a hospital must have to receive a mortality measure score. If this change is finalized, fewer hospitals would have an outcomes domain score and therefore may not receive a total performance score under the VBP program. Thus, CMS seeks to modify the requirements for a total performance score to include as many hospitals as possible in the VBP program.

12. Applicability of the VBP Program to Hospitals

CMS proposes to modify the requirements for a state with a waiver under section 1814(b)(3), namely Maryland, to seek an exemption for its hospitals from the VBP program if certain conditions are meant. Under the process established in previous rules, Maryland hospitals are exempt from the VBP program for FY 2013. CMS proposes that for FY 2014 and beyond, the state would need to submit the required report supporting an exemption request by November 15 prior to the effective fiscal year.

13. Minimum Cases and Measures for FY 2015

Under the VBP program, a hospital must meet a minimum number of cases to receive a score on a measure and must have scores on a minimum number of measures to receive a score for a domain. For clinical process of care measures, a hospital must have a minimum of 10 cases for a measure score and 4 measures for a domain score. For

HCAHPS, a 100-completed survey minimum applies, and for the 30-day mortality measures a 10-case minimum applies for each measure and a minimum of 2 measures is required for an outcomes domain score.

Beginning in FY 2015, CMS proposes to modify the minimum number of cases required for a hospital to receive a score on the 30-day mortality measures, and proposes a minimum for the Efficiency domain. A minimum number of 25 cases would be required for a score on the mortality measures, replacing the current 10-case minimum. In light of the proposal described earlier for a 9-month performance period for these measures for FY 2015, CMS believes an increase in the minimum number of cases will ensure more reliable data given the shorter time period. Although fewer hospitals would receive a mortality domain score, CMS notes that it has also proposed that hospitals need only have a score for two domains to receive a total VBP score.

For the new efficiency measure, CMS proposes a minimum of 25 cases be required for a score on his measure, and since it is the only measure, a score for the Efficiency domain. CMS describes an independent analysis it used to determine the appropriate minimum, and says that at 25 cases, 97.8 percent of hospitals would meet the minimum to receive a score, and the 95 percent confidence interval for a hospital with an efficiency score of 1.0 is from 0.81 to 1.23. By contrast, the analysis found that at a 50 case minimum, 95.9 percent of hospitals would receive a score and the 95 percent confidence interval range would be 0.86 to 1.16.

14. Immediate Jeopardy Citations

The statute requires that a hospital be excluded from the VBP program if it has been cited by the Secretary during the performance period for deficiencies that pose an immediate jeopardy to the health or safety of patients. In this rule, CMS proposes that for purposes of the VBP program, the definition of the term "immediate jeopardy" found under 42 CFR Part 489 and used for the purposes of survey, certification, enforcement and termination procedure with respect to provider agreements would apply. In addition, CMS proposes to define the phrase "cited for deficiencies that pose immediate jeopardy" for the purposes of the VBP program as the identification of an immediate jeopardy noted on the Form CMS-2567, Statement of Deficiencies and Plan of Correction that is issued to a hospital after a survey. A hospital would need to be cited for immediate jeopardy on two surveys during the performance period each time noted on the Form CMS-2567 in order to be considered having multiple deficiencies that pose immediate jeopardy and thus excluded from the VBP program for the applicable fiscal year. Because performance periods can vary by measure, CMS indicates that a hospital cited for multiple deficiencies as defined here during any of the performance periods for a VBP program year would be subject to exclusion. The preamble discusses alternative definitions that were considered. **CMS welcomes comments on these proposed definitions.**

VBP Program Quality Measures for FY 2014 and Proposed for FY 2015			
Measure ID	**Measure Description**	**2014 (Previously Finalized)**	**2015 (Proposed)**
Process of Care Measures			
AMI-7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival	X	X
AMI-8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	X	X
AMI-10	Statin Prescribed at Discharge		X
HF-1	Discharge Instructions	X	X
PN-3b	Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital	X	X
PN-6	Initial Antibiotic Selection for CAP in Immunocompetent Patient	X	X
SCIP-Inf-1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision	X	X
SCIP-Inf-2	Prophylactic Antibiotic Selection for Surgical Patients	X	X
SCIP-Inf-3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time	X	X
SCIP-Inf-4	Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose	X	X
SCIP-Inf-9	Postoperative Urinary Catheter Removal on Post Operative Day 1 or 2	X	X
SCIP–Card-2	Surgery Patients on a Beta Blocker Prior to Arrival That Received a Beta Blocker During the Perioperative Period	X	X
SCIP-VTE-1	Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered	X	
SCIP-VTE-2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery	X	X
Patient Experience of Care Measures			
Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS)			
Communication with Nurses		X	X
Communication with Doctors		X	X
Responsiveness of Hospital Staff		X	X
Pain Management		X	X
Communication About Medicines		X	X
Cleanliness and Quietness of Hospital Environment		X	X
Discharge Information		X	X
Overall Rating of Hospital		X	X
Outcome Measures			

VBP Program Quality Measures for FY 2014 and Proposed for FY 2015			
Measure ID	**Measure Description**	**2014 (Previously Finalized)**	**2015 (Proposed)**
MORT-30-AMI	Acute Myocardial Infarction (AMI) 30-Day Mortality Rate	X	X
MORT-30-HF	Heart Failure (HF) 30-Day Mortality Rate	X	X
MORT-30-PN	Pneumonia (PN) 30-Day Mortality Rate	X	X
AHRQ PSI composite	Complication/patient safety for selected indicators (composite)		X
CLABSI	Central Line-Associated Blood Stream Infection		X
Efficiency Measures			
MSPB-1	Medicare spending per beneficiary		X

D. Long-Term Care Hospital Quality Reporting Program

This rule proposes measures and data collection timelines for the LTCH quality reporting program that was established in the FY 2012 IPPS/LTCH final rule. Information on the quality reporting program is available at http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html?redirect=/ltch-quality-reporting
Under the FY 2012 IPPS/LTCH final rule, three measures were adopted for the LTCH quality reporting program for the FY 2014 payment determination, the initial year of the quality reporting program. Two of them, CAUTI (NQF #0138) and CLABSI (NQF #0139), are measures in use in the hospital IQR program and other quality reporting programs. The third (NQF # 0678) measures the percent of residents with pressure ulcers that are new or worsened.

CMS makes several proposals regarding measures previously adopted for the LTCH quality reporting program:

- The three measures previously adopted for the FY 2014 payment determination would continue into FYs 2015 and 2016.
- For the future, once a quality measure is adopted, it would be retained in future years unless otherwise stated.
- The changes to the CLABSI and CAUTI measures made in the NQF measure maintenance process subsequent to the adoption of these measures for the FY 2014 payment determination would be adopted for the LTCH quality reporting program.
- CMS proposes that changes to measure specifications made in the NQF measure maintenance process that do not substantially change the nature of the measure would be made through a subregulatory process. Rulemaking would continue to be used to adopt substantial changes to measures.

CMS proposes that the following five additional measures be included in the LTCH quality reporting program for the FY 2016 payment determination.

1. Percent of Nursing Home Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680).
2. Percent of Residents Assessed and Appropriately Given the Pneumococcal Vaccine (Short-Stay) (NQF #0682)

In discussing the proposed addition of these vaccine measures, CMS cites the prevalence of influenza and pneumococcal disease among the elderly and indicates that although they have been endorsed by NQF for short-stay nursing home residents, these measures are relevant to patients in the LTCH setting. Therefore, CMS is using the authority for selecting non-NQF measures to propose the addition of these measures to the LTCH quality reporting program. CMS proposes that data submission for these measures would be accomplished through the LTCH CARE Data Set, the quality reporting infrastructure to be used for the measures adopted for the FY 2014 payment determination. Measure specifications are available at https://www.cms.gov/NursingHomeQualityInits/Downloads/MDS30QM-Manual.pdf.

3. Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431)

This measure of the percentage of healthcare personnel who receive the influenza vaccine has previously been adopted for use in the Hospital IQR Program and the ASC quality reporting program. CMS indicates that the measure is applicable to the LTCH setting. This measure would be reported through the NHSN. Measure specifications and data submission information are available at http://www.cdc.gov/nhsn.

4. Ventilator Bundle (NQF #0302)

This measure, which is NQF endorsed for ICU patients in the acute care setting, is proposed by CMS for addition to the LTCH quality reporting program under the authority for selecting non-NQF measures. CMS cites ventilator associated pneumonia as a costly, deadly infection that is the most common diagnosis in LTCHs. The measure consists of four components, (1) head of the bed elevation >30^{o}; (2) daily sedation interruption and assessment of readiness to wean; (3) peptic ulcer disease (PUD) prophylaxis; and (4) deep vein thrombosis (DVT) prophylaxis. CMS reports that a fifth element, daily oral care with Chlorhexidine, has been recommended for addition to the measure. CMS proposes that this measure would be reported through the LTCH CARE Data Set.

5. Restraint Rate per 1,000 Patient Days (not NQF endorsed).

CMS discusses issues regarding the use of patient restraints, and indicates that its measure development contractor convened a technical expert panel to review measures related to restraints, one of which was reviewed by the MAP, but CMS subsequently determined that the look back and monitoring periods are problematic for use in the LTCH setting. The proposed measure was developed by the National Association of Long Term Hospitals and is used by some LTCHs participating in the Association's Health Information System. Because it is specified for LTCHs, CMS believes this measure addresses concerns raised regarding the patient restraint measures endorsed by

NQF for other settings. CMS proposes that this measure be reported through the LTCH Care Data Set.

Proposed data submission deadlines are shown in the table that follows. CMS proposes that for the FY 2015 payment determination, LTCHs would have about 135 days after the end of the reporting quarter to submit data to CMS. For FY 2016 and subsequent years, the time frame would be 45 days after the end of the reporting quarter.

Timelines for Data Submission for the LTCH Quality Reporting Program	
FY 2014 Payment Determination (finalized in FY 2012 IPPS/LTCH rulemaking)	
Data Collection Timeframe (CY 2012)	**Final Submission deadline**
Q4 (October 1-December 31, 2012)	May 15, 2013
FY 2015 Payment Determination (Proposed)	
Data Collection Timeframe (CY 2013)	**Final Submission deadline**
Q1 (January -March 2013)	August 15, 2013
Q2 (April- June 2013)	November 15, 2013
Q3 (July –September 2013)	February 15, 2014
Q4 (October –December 2013)	May 15, 2014
FY 2016 Payment Determination (Proposed)	
Data Collection Timeframe (CY 2014)	**Final Submission deadline**
Q1 (January -March 2014)	May 15, 2014
Q2 (April- June 2014)	August 15, 2014
Q3 (July –September 2014)	November 15, 2014
Q4 (October –December 2014)	February 15, 2015

Public Display of Data Quality Measures. At this time, CMS is not proposing any procedures or timelines for public reporting of data reported under the LTCH quality reporting program. The statute requires that the data must be made available to the public, that LTCHs must have the opportunity to review the data prior to its public release, and that the data must be posted on the CMS website. Given the timelines for data submission, CMS will presumably take this up in future rulemaking, although the proposed rule does not indicate when.

E. Quality Reporting Requirements for Ambulatory Surgical Centers

A quality reporting program was finalized in the 2012 OPPS/ASC Final Rule for initial implementation in CY 2014. At that time CMS indicated that the FY 2013 IPPS/LTCH rulemaking process would be used to further address elements of the program regarding administrative requirements, data validation, and reconsiderations and appeals. The IPPS/LTCH rule was chosen for this purpose because it will be finalized at an earlier date than the OPPS/ASC rule.

The measures previously adopted for the ASC quality reporting program for 2014 include several measures which are to be reported by ASCs by adding a Quality Data Code (QDC) to the claim. For 2015, these measures will continue as part of the

program and two structural measures will also be required to be reported by participating ASCs.

The proposals in this rule regarding ASC quality reporting are:

- ASCs are encouraged to maintain a QualityNet administrator as a point of contact for security purposes for the program, but this is only a requirement for the purpose of reporting the structural measures required for 2015, which must be submitted between July 1, 2013 and August 15, 2013.
- ASCs are considered to be participating in the quality reporting program for a payment determination year if they submit any quality data during the reporting period for that year, and participation would be assumed to continue until the ASC formally withdraws from the program. Withdrawal must be done by August 15th of the year prior to the payment determination year. Once an ASC withdraws for a payment year, the 2.0 percentage point reduction in the annual payment update would take effect for that year.
- All quality data submitted by an ASC would be publicly available unless the ASC withdraws from the program.
- Administrative requirements would apply to ASCs designated as open in the CASPER system before January 1, 2012 for 2014 payment determination and January 1, 2013 for the 2015 payment determination.
- Claims for the time period October 1, 2012 to December 31, 2012 that are paid by April 30, 2013 would be included in the data used for the 2014 payment determination.
- To be considered complete for the 2014 and 2015 payment determinations, ASCs would have to report QDCs on at least 50% of claims meeting measure specifications. CMS expects to propose increasing this threshold for future years as ASCs become more familiar with the quality reporting requirements.
- No data validation involving independent medical record review is proposed. CMS believes this is consistent with other quality reporting programs, where claims-based and structural measures are not subject to such data validation.
- A process is proposed for waivers or extensions of the ASC reporting requirements under extraordinary circumstances. The process parallels the one used for the hospital OQR program.
- A process for reconsideration of quality reporting program payment determinations is proposed similar to the ones in effect for the hospital IQR and OQR programs.

F. Inpatient Psychiatric Facilities Quality Reporting Program

CMS proposes to implement an inpatient psychiatric facilities (IPF) quality reporting program beginning in FY 2014. The proposed rule reviews the statutory authority and requirements for this program. The program will apply to psychiatric hospitals and units that are reimbursed under Medicare's IPF PPS. Under the statute, covered entities that do not meet the requirements of the IPF quality reporting program for a fiscal year

would be subject to a 2.0 percentage point reduction in the applicable annual update factor, and this reduction may result in a negative update factor. CMS invites comments on the regulatory language proposed to implement this requirement.

Proposed Measures

For the IPF quality reporting program in FY 2014 and subsequent years, CMS proposes six quality measures. The proposed rule includes a lengthy discussion of the factors that CMS considered in selecting quality measures for the IPF quality reporting program. CMS believes the proposed measures are consistent with the National Quality Strategy, are tailored to improving quality in IPFs, promote alignment of quality objectives across provider settings, and minimize reporting burden on IPFs. With respect to reporting burden, CMS believes that more than one-quarter of IPFs are already reporting the data needed to calculate the proposed measures to The Joint Commission for accreditation purposes.

The six proposed measures are listed below. For all the proposed measures, CMS proposes to collect aggregate data rather than patient-level data to minimize reporting burden on IPFs. CMS intends to provide a template in a commonly available spreadsheet format to assist providers in entering and computing measure rates.

Patient Safety

HBIPS-2 Hours of Physical Restraint Use (NQF #0640)
This measure is the total number of hours that all psychiatric inpatients were maintained in physical restraints, expressed as a percentage of the total number of psychiatric inpatient hours, excluding leave days.

HBIPS-3 Hours of Seclusion Use (NQF #0641)
The total number of hours that all psychiatric inpatients were held in seclusion, expressed as a percentage of the total number of psychiatric inpatient hours, excluding leave days.

Clinical Quality of Care

HBIPS-4 Patients Discharged on Multiple Antipsychotic Medications (NQF #0552)

HBIPS-5 Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification (NQF #0560)

These two measures were developed to be used together. HBIPS-4 measures the percentage of all psychiatric discharges who are discharged on two or more routinely scheduled antipsychotic medications, while HBIPS-5 measures the rate patients discharged on multiple antipsychotic medications with appropriate justification. CMS believes that while lower rates of multiple antipsychotic are indicative of higher quality care, there is no expectation that a zero rate is the desired outcome.

Care Coordination

HBIPS-6	Post-Discharge Continuing Care Plan Created (NQF #0557)
HBIPS-7	Post-Discharge Continuing Care Plan Transmitted to Next Level of Care Provider Upon Discharge (NQF #0558)

These two measures were also developed as a pair. HBIPS-6 measures the percentage of all psychiatric discharges for whom a post-discharge continuing plan is created and contains the reason for hospitalization, principal discharge diagnosis, discharge medications and next level of care recommendations. HBIPS-7 measures the percentage of all psychiatric discharges for whom the post-discharge plan of care was transmitted to the next level of care.

All the proposed measures are NQF endorsed and specifications are available from The Joint Commission, which developed them at http://manual.jointcommission.org/releases/TJC2012A/HospitalBasedInpatientPsychiatricServices.html.

CMS welcomes comments on additional quality measures and measures topics for possible future addition to the IPF quality reporting program. CMS encourages measure developers to consider conforming measures to EHR standards where appropriate, noting that this is not applicable for the proposed measures which would be submitted on aggregate data only.

Data Submission Requirements for the FY 2014 Payment Determination and Subsequent Years

CMS intends to provide a user manual, to be posted on the QualityNet.org website that will contain information needed by IPFs to participate in the quality reporting program, including links to measure specifications and data submission information. As it does elsewhere in this rule for other quality reporting programs, CMS proposes that changes to measure specifications made in the NQF measure maintenance process that do not substantially change the nature of the measure would be made through a subregulatory process. Rulemaking would continue to be used to adopt substantial changes to measures.

IPFs would be required to submit data using a web-based measures tool found in the IPF section of the QualityNet.org website. Data must be submitted on all measures to meet the program requirements. The proposed data submission deadlines are shown in the following table.

Proposed Timelines for Data Submission for the IPF Quality Reporting Program	
FY 2014 Payment Determination	
Reporting Period (services provided)	**Submission Timeframe**
Q4 2012 (October 1-December 31, 2012)	July 1, 2013- August 15, 2013
Q1 2013 (January1-March 31, 2013)	
FY 2015 Payment Determination	
Reporting Period (services provided)	**Submission Timeframe**

Proposed Timelines for Data Submission for the IPF Quality Reporting Program	
Q2 (April- June 2013)	July 1, 2014- August 15, 2014
Q3 (July –September 2013)	
Q4(October –December 2013)	
FY 2016 Payment Determination	
Reporting Period (services provided)	**Submission Timeframe**
Q1 (January -March 2014)	July 1, 2015-August 15, 2015
Q2 (April- June 2014)	
Q3 (July –September 2014)	
Q4(October –December 2014)	

Requirements for population, sampling, and minimum case thresholds would be those specified for the proposed measures in The Joint Commission's Specifications Manual. Data would be reported on all patients, not just Medicare beneficiaries. IPFs would be required to submit data on all measures, even when the population is zero or small or if no cases apply (e.g., no hours of physical restraint use). CMS proposes that when where a measure rate is calculated on a small number of cases this would be clearly noted when the data are publicly displayed.

IPFs would be required to submit a data accuracy and completeness acknowledgement by August 15th each year via the QualityNet website. For example, for the FY 2014 payment determination, the acknowledgement deadline would be August 15, 2013.

Other Procedural Requirements

Procedural requirements for IPF participation parallel those of the Hospital IQR Program, involving registering with QualityNet, completing a notice of participation, and so forth. Reconsideration and appeals procedures would be available to an IPF that believes its annual payment update was incorrectly reduced for failure to meet the quality reporting program requirements, and waivers from the quality reporting program requirements would be available to IPFs under extraordinary circumstances. The proposed rule details these procedures.

Public Display of Quality Data

CMS proposes that, as required by the statute, data submitted under the IPF quality reporting program be made publicly available. CMS proposes to make the data publicly available on its website beginning in the first quarter of the calendar year following the payment determination year. For example, data for the FY 2014 payment determination year would be displayed during the first quarter of CY 2014. IPFs would have the opportunity to preview the data between September 20 and October 19 of the payment determination year, before it is publicly displayed.

IX. Proposed Quality Improvement Organization (QIO) Regulation Changes Related to Provider and Practitioner Medical Record Deadlines and Claims Denials

Medical records are critical for Quality Improvement Organizations (QIOs) to determine that services were reasonable and medically necessary, meet professionally recognized quality standards, and were provided in the appropriate settings. CMS states that the responsibility of practitioners and providers to supply information to QIOs for use in completing their review activities is implicit throughout the QIO program. However, CMS is proposing several changes to the regulations at § 476.1, 476.78, and 476.90 to more clearly convey the responsibilities of providers and practitioners in submitting medical information and to specify the QIO's authority should the information not be received.

Proposals related to the definition of "providers":

- Add a definition of "providers" under § 476.1 to clearly denote that certain requirements in Part 476 apply to health care facilities, institutions, and organizations involved in the delivery of health care services to Medicare beneficiaries.

- Change the section heading of § 476.78 from "Responsibilities of health care facilities" to "Responsibilities of providers and practitioners".

Proposals related to the timeframes for practitioners and providers to follow in submitting medical information:

- Add references to "practitioners" in § 476.78(b)(2) so that the 21-day and 30-day timeframes for submittal of information apply equally to practitioners and providers.

Proposals to make changes to § 476.90 that will provide improved instructions to QIOs when attempting to resolve issues associated with practitioners and providers that fail to submit medical information within the timeframes set forth in § 476.78. These include:

- Changing the section heading from "Lack of cooperation by a health care facility or practitioner" to "Lack of cooperation by a provider or practitioner".

- Incorporating the broader term "provider" (as reflected in the proposed changes to § 476.1) within § 476.90 as well as references to "practitioners", where appropriate.

- Adding references to "practitioners" in § 476.90(a)(2) to denote that the QIO's authority includes the ability to make financial liability determinations for both providers and practitioners and adding the word "may" to clarify that the QIO has the discretion to report to the Inspector General a provider's or practitioner's failure to provide evidence of the medical necessity or quality of care provided.

- Modifying § 476.90(b) to denote that QIOs will also deny claims if practitioners fail to submit medical information as requested. This proposed change is based on the fact that a QIO cannot make a determination about whether payment shall be made on the

basis of its reviews (section 1154(a)(2) of the Act) if the QIO does not have the medical records it needs to determine that payment would be appropriate.

- Adding new language to § 476.90(b) to convey the right of providers and practitioners to request a reconsideration by the QIO of its decision to deny the claim based on the failure to receive the medical information, and that no further appeal rights exist beyond the QIO.

Proposed technical changes:

- A technical correction to a cross-reference to "§ 474.30(c)" that appears in § 476.90(a)(1). This cross-reference is to the Office of Inspector General regulations that convey the obligations of providers and practitioners; these regulations are now located in 42 CFR 1004.10(c).

- A minor technical change to § 476.78, that is unrelated to the application of time frames. CMS proposes to delete the sentence, "QIOs pay providers paid under the prospective payment system for the costs of photocopying records required by the QIO in accordance with the payment rate determined under the methodology described in paragraph (c) of this section and for first-class postage for mailing the records to the QIO", because it is merely a reference to paragraph (c) of § 476.78 and does not provide substantive information.

CMS invites public comment on these proposals.

Appendix A. History of Documentation and Coding Adjustment

FY 2008 and FY 2009. When the transition to MS-DRGs began in FY 2007, CMS projected that the average case-mix index (CMI) would increase, especially in the initial years, due to improved medical record documentation as well as more complete and accurate coding. CMI changes of this nature increase payments to hospitals, but they do not reflect the type of real increases in the severity of cases that require additional hospital resources. CMS actuaries estimated that maintaining budget neutrality required an adjustment of -4.8 percent to the national standardized amount. In the FY 2008 final rule, CMS phased in this -4.8 percent adjustment over 3 years, with prospective documentation and coding adjustments scheduled to be -1.2 percent in FY 2008, -1.8 percent in FY 2009, and -1.8 percent in FY 2010.

Responding to hospital concerns, on September 29, 2007 Congress enacted the Transitional Medical Assistance, Abstinence Education, and Qualifying Individuals Programs Extension Act of 2007 (P. L. 110-90). Section 7(a) of the law reduced the documentation and coding adjustment to -0.6 percent for FY 2008 and -0.9 percent for FY 2009, but did not address the FY 2010 adjustment of -1.8 percent. To implement these changes, CMS promulgated a final rule on November 27, 2007 (72 FR 66886).

In the final rule for FY 2009, CMS applied a documentation and coding adjustment of -0.9 percent to the national standardized amounts as required by P.L. 110-90. Because the documentation and coding adjustments established in the FY 2008 IPPS final rule were cumulative, the -0.9 percent adjustment in FY 2009 was in addition to the -0.6 percent adjustment in FY 2008, yielding a combined effect of -1.5 percent for FY 2009. The adjustments made in FYs 2008 and 2009 are carried forward and affect future standardized amounts.

FY 2010. P. L. 110–90 requires the Secretary to make adjustments in fiscal years 2010 to 2012 to the extent that case-mix changes due to improved documentation and coding differ from the level assumed in the prospective adjustments made by Congress. Two types of corrections are required. Section 7(b)(1)(A) of P. L. 110–90 requires an appropriate adjustment to the extent that the Secretary determines that actual changes in documentation and coding during FY 2008 or FY 2009 are different than the prospective adjustments that were applied, using the authority of section 1886(d)(3)(A)(vi) of the Act to adjust the average standardized amounts for subsequent fiscal years in order to eliminate the effect of such coding or classification changes. These adjustments are intended to ensure that future annual aggregate IPPS payments are the same as the payments that otherwise would have been made had the prospective adjustments in FY 2008 and FY 2009 reflected the change that actually occurred in those years.

Similarly, if the Secretary determines, based on a retroactive evaluation of claims data, that changes in documentation and coding during FY 2008 or FY 2009 are different from the prospective adjustments, then section 7(b)(1)(B) of P. L. 110-90 requires the Secretary to make an additional adjustment to the standardized amounts. This adjustment must offset the estimated increase or decrease in aggregate payments for FYs 2008 and 2009 (including interest) resulting from the difference between the actual documentation and coding effect

and the documentation and coding adjustments which were applied in the respective fiscal years.

For the FY 2010 proposed rule, CMS estimated the documentation and coding increase in FY 2008 to be 2.5 percent. The analyses were repeated for the final rule using more complete FY 2008 MedPAR data (claims processed through March 2009 versus claims processed through December 2008) and the results did not change. The proposed rule reduced the national standardized amounts by 1.9 percent to satisfy the requirement of section 7(b)(1)(A) of P. L. 110-90 to correct IPPS rates going forward, but delayed recovery of the additional FY 2008 payments made in FY 2008 due to the underestimate of the prospective adjustment. CMS stated it would wait for more complete data and make the necessary recoveries in FYs 2011 and 2012. CMS estimated that these additional payments amounted to approximately $2.2 billion.

In the FY 2010 final rule, CMS chose not to make any prospective or retrospective adjustments in FY 2010 for documentation and coding-related increases occurring in FY 2008. The final rule stated, *"we believe that it would be more prudent to delay implementation of the documentation and coding adjustment to allow for a more complete analysis of FY 2009 claims data. If the estimated documentation and coding effect determined based on a full analysis of FY 2009 claims data is more or less than our current estimates, it would change, possibly lessen, the anticipated cumulative adjustments that we currently estimate we would have to make for FY 2008 and FY 2009 combined adjustment."* CMS also indicated that it would consider applying a prospective adjustment based upon a complete analysis of FY 2008 and FY 2009 claims data over an extended time period, such as 5 years, beginning in FY 2011. During this phase-in, the agency also would address any difference between the documentation and coding-related case-mix increase in FY 2009 and the -0.9 percent prospective documentation and coding adjustment applied in FY 2009 under section 7(a) of P. L. 110-90.

In the FY 2010 rulemaking, CMS noted that the additional adjustments that P. L. 110-90 requires for fiscal years 2011 and 2012 could be substantial. It estimated that the total adjustments that could be required over the 3-year period FY 2010 to FY 2012 was a reduction of 8.5 percent.

FY 2011 Proposed Rule

For the FY 2011 proposed rule, CMS performed the same analysis on FY 2009 claims data and used the same methodology as it did on FY 2008 claims data for the FY 2010 proposed and final rules. Based on its analysis, CMS estimated that the documentation and coding increase in FY 2009 not reflective of real changes in case-mix was 5.4 percent. Compared to the prospective adjustments of 0.6 and 0.9 percentage points made in FYs 2008 and 2009 respectively, for a cumulative prospective adjustment of 1.5 percentage points, the actual 5.4 percent increase in FY 2011 represents a gap of 3.9 percentage points. Thus, the proposed rule stated that 3.9 percent of FY 2009 payments represent excess payments to be recovered – about $6.9 billion, with appropriate interest as required by law. Combined with the 1.9 percent in excess FY 2008 payments (about $2.2 billion) stemming from a documentation and coding increase of 2.5 percentage points in FY 2008 compared to a 0.6 percentage point prospective

adjustment in that year, CMS reported that the total amount of excess payments to be recovered is 5.8 percent – or about $9.1 billion plus interest.

Section 7(b)(1)(B) of Pub. L. 110-90 requires CMS to recover the excess payments by the end of FY 2012. The FY 2011 proposed rule reduced the PPS standardized amounts by 2.9 percentage points in FY 2011 to recover about one-half of the excess payments. The adjustment to the standardized amounts is temporary. CMS anticipates removing it from the rates in FY 2012, when it would also be necessary under current law to apply the remaining approximately -2.9 percent adjustment required by section 7(b)(1)(B) of Pub. L. 110-90. These two steps in FY 2012, restoring the -2.9 percent adjustment made in FY 2011, and applying the remaining adjustment of approximately -2.9 percent, would effectively cancel each other out. The result would be an aggregate adjustment of approximately 0.0 percent (subject to the need to account for accumulated interest) in FY 2012.

As noted, Section 7(b)(1)(A) of Pub. L. 110-90 requires CMS to make prospective adjustments to correct the rates going forward in order to avoid making future excess payments. Through FY 2009, the cumulative increase in documentation and coding not reflective of real CMI increase is 5.4 percentage points and the cumulative prospective adjustment made through FY 2009 is 1.5 percentage points, leaving 3.9 percentage points to be made in future prospective adjustments. In the proposed rule, CMS states that the law grants discretion concerning when to make these prospective adjustments – and no adjustment were proposed for FY 2011.

FY 2011 Final Rule

In comments on the proposed rule, MedPAC reported corroborating analyses and supported both CMS' analysis and conclusions concerning the effect of documentation and coding changes. The American Hospital Association (AHA) and other hospital groups, however, strongly disagreed with the CMS analysis on grounds that it considered only one year of data and thus failed to account for what is a long-term trend in case-mix increase pre-dating implementation of MS-DRGs. They submitted an analysis of multiple years of Medicare claims to show that a significant portion of the change which CMS found actually is the continuation of historical trends, rather than the effect of documentation and coding changes due to implementation of MS-DRGs. Their analysis found a documentation and coding effect of 0.9 percent for FYs 2008 and 2009. The AHA comments also included corroborating trend analyses of the percentage of Medicare discharges involving the ICU, of data from the Medical Expenditure Panel Survey (MEPS), and of data from the Healthcare Cost and Utilization Project (HCUP). Each of these indicated an historical pattern of case-mix increase.

CMS rejected the hospitals' comments on two grounds. It said that its direct analytical approach is more reliable than the trend analysis – and it noted that the law does not require the agency to use a specific methodology. Second, it said that trend analysis is sensitive to the time period selected for the analysis and of the cohort of hospitals which are included – in this case, whether all critical access hospitals were excluded from the analysis. It presented data from a MedPAC analysis showing case-mix change from 1998 to 2009 in which the annual change from 1998-2001 was negative each year. The first year in the AHA analysis was 2001 and CMS speculated that the AHA case-mix trend line would be lower if the earlier years were

included. The final rule adopts the proposal to reduce the FY 2011 standardized amount by -2.9 percent, representing approximately one-half of the aggregate recoupment adjustment required under section 7(b)(1)(B) of Pub. L. 110-90.

The table below shows the aggregate level of adjustments that are required by law (9.7 percentage points) and the amount that would remain to be recovered (6.8 percentage points) in FY 2012 and future years.

FY 2011 MS-DRG Documentation and Coding Adjustment

	Required Prospective Adjustment fo FYs 2008-2009	Required Recoupment Adjustment for 2008-2009	Total Adjustm	Proposed Recoupment Adjustment for FY 2011	Remaining Adjustment
Level of Adjustments	-3.9	-5.8	-9.7	-2.9	-6.8

Noting the absence of any prospective adjustment to the rates, MedPAC's comments expressed concern about the "progressive accumulation in overpayments, which cannot be recovered based upon current statutory authority." MedPAC recommended completing the retrospective adjustment in FY 2012, with accumulated interest, to fulfill the requirements of section 7(b)(1)(B) of Pub. L. 110-90 and then making additional prospective adjustments in that year of -2.0 percent. CMS states simply that it has not yet made a formal proposal for FY 2012 but notes that the two steps contemplated for FY 2012, restoring the FY 2011 -2.9 percent adjustment and then applying the remaining adjustment of approximately -2.9 percent, would effectively cancel each other out. The result would be an aggregate adjustment of approximately 0.0 percent (subject to the need to account for accumulated interest).

Applying adjustments to the hospital-specific and Puerto Rico-specific rates

In the FY 2009 IPPS final rule, CMS concluded that it has authority to apply the documentation and coding adjustment to the hospital-specific rates applicable to sole community hospitals (SCHs) and Medicare-dependent, small rural hospitals (MDHs) using the special exceptions and adjustment authority under section 1886(d)(5)(I)(i) of the Act. CMS said that it would examine FY 2008 claims data for evidence of significant increases in case mix and would consider proposing an adjustment for documentation and coding-related increases in its rulemaking for FY 2010.

Similarly, CMS concluded in the FY 2009 IPPS final rule that it could use the special exceptions authority to apply a documentation and coding adjustment to the 25 percent Puerto Rico-specific portion of the PPS payment for hospitals in Puerto Rico. (The other 75 percent of the payment for these hospitals is based on the national IPPS rate.) It said it would evaluate FY 2008 claims data and consider application of the adjustment to the Puerto Rico standardized amount in rulemaking for FY 2010. MedPAC supported application of the documentation and coding adjustment to the hospital-specific and Puerto Rico-specific rates, but many other commenters were opposed, some citing a lack of legal authority.

FY 2010. CMS' retrospective evaluation of the FY 2008 claims data for SCHs and MDHs using the same methodology as for other IPPS hospitals found that, independently for both SCHs and MDHs, the documentation and coding-related case-mix increase during FY 2008 slightly exceeded the 2.5 percent result discussed earlier for all hospitals, but did not significantly differ from that result. Therefore, the FY 2010 proposed rule would have reduced the hospital-specific rate by 2.5 percent. The hospital-specific reduction of 2.5 percent was larger than the 1.9 percent reduction applicable to other IPPS hospitals because the prospective adjustment of -0.6 percent was not applied to the hospital-specific rate. A similar analysis for Puerto Rico hospitals found that the documentation and coding-related increase during FY 2008 was approximately 1.1 percent. Based on its findings, CMS proposed to reduce the Puerto Rico-specific rate by 1.1 percent in FY 2010.

Following the pattern established by postponing the FY 2010 adjustment for IPPS hospitals generally, the FY 2010 final rule delayed implementation of the documentation and coding-related adjustment for both the hospital-specific and Puerto Rico-specific rates to allow for a more complete analysis of FY 2009 claims data. CMS said that it would consider a phase-in of the adjustment over an appropriate period, beginning in FY 2011.

FY 2011 Proposed and Final Rules. CMS' best estimate of the documentation and coding increase (not reflective of real CMI increase) in discharges from SCHs and MDHs yields a result similar to the experience of IPPS hospitals generally. Thus, a cumulative adjustment of -5.4 percent is required to eliminate the full effect of the documentation and coding changes on future payments. Unlike the case of standardized amounts paid to IPPS hospitals, CMS has not made any previous adjustments to the hospital-specific rates paid to SCHs and MDHs so that the entire -5.4 percent adjustment remains to be implemented. In the proposed and final rules for FY 2011, CMS decided to phase in the adjustment by reducing the hospital-specific rate applicable to SCHs and MDHs in FY 2011 by 2.9 percent, slightly more than one-half of the total 5.4 percentage point reduction that is required. The 2.9 percent reduction is a prospective adjustment that will be carried forward into future years' rates.

Similarly, CMS' analysis of FY 2009 claims data for the final rule found that a cumulative adjustment of -2.6 percent is required to eliminate the full effect of the documentation and coding changes on future payments from the Puerto Rico-specific rate. Data available for the proposed rule analysis had showed that a cumulative adjustment of -2.4 percent was needed. The final rule removes the full 2.6 percent from Puerto Rico-specific rates in FY 2011 in a prospective adjustment that will carry forward to future years. CMS notes that the -2.6 percent adjustment represents the full adjustment that is warranted for the Puerto Rico-specific rate and that it does not anticipate proposing any additional adjustments.

Appendix B: Regulatory Impact Analysis –Table

TABLE I.— IMPACT ANALYSIS OF PROPOSED CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2013

	No. of Hospitals[1]	Proposed Hospital Rate Update and Documentation and Coding Adjustment[2]	Proposed FY 2013 Weights and DRG Changes with Application of Recalibration Budget Neutrality[3]	Proposed FY 2013 Wage Data with Application of Wage Budget Neutrality[4]	Proposed FY 2013 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[5]	Proposed FY 2013 MGCRB Reclassifications[6]	Proposed Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality[7]	Proposed Application of the Frontier Wage Index[8]	Proposed FY 2013 Out-Migration Adjustment[9]	Expiration of MDH Status[10]	Proposed Hospital Readmissions Reduction Program[11]	All Proposed FY 2013 Changes[12]
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
All Hospitals	3,405	2.2	0.0	0.0	0.0	0.0	0.0	0.1	0.0	-0.1	-0.3	0.9
By Geographic Location:												
Urban hospitals	2,485	2.3	0.0	0.0	0.1	-0.2	0.0	0.1	0.0	0.0	-0.3	1.0
Large urban areas	1,365	2.3	0.0	0.2	0.2	-0.3	0.0	0.0	0.0	0.0	-0.3	1.2
Other urban areas	1,120	2.3	0.0	-0.2	-0.1	-0.1	0.1	0.1	0.0	-0.1	-0.2	0.9
Rural hospitals	920	1.8	-0.1	-0.3	-0.3	2.1	-0.3	0.0	0.1	-0.9	-0.3	-0.5
Bed Size (Urban):												
0-99 beds	627	2.3	0.0	0.1	0.2	-0.6	0.2	0.2	0.0	-0.4	-0.2	1.0
100-199 beds	773	2.3	0.0	0.1	0.2	0.0	0.3	0.0	0.0	-0.1	-0.3	1.1
200-299 beds	448	2.3	0.0	0.1	0.1	-0.2	0.0	0.1	0.0	0.0	-0.3	1.2
300-499 beds	432	2.3	0.0	0.0	0.0	-0.2	0.0	0.1	0.0	0.0	-0.3	1.2
500 or more beds	205	2.3	0.0	-0.1	0.0	-0.3	-0.1	0.0	0.0	0.0	-0.3	0.8
Bed Size (Rural):												
0-49 beds	317	1.8	-0.1	-0.3	-0.4	0.8	-0.3	0.1	0.3	-1.4	-0.3	-1.9
50-99 beds	346	1.7	-0.1	-0.3	-0.4	1.2	-0.3	0.0	0.2	-2.2	-0.3	-2.4
100-149 beds	152	1.8	-0.1	-0.3	-0.3	2.6	-0.3	0.0	0.0	-0.3	-0.4	0.3
150-199 beds	58	1.8	-0.1	-0.2	-0.3	2.3	-0.3	0.1	0.0	0.0	-0.3	0.6

	No. of Hospitals[1]	Proposed Hospital Rate Update and Documentation and Coding Adjustment[2]	Proposed FY 2013 Weights and DRG Changes with Application of Recalibration Budget Neutrality[3]	Proposed FY 2013 Wage Data with Application of Wage Budget Neutrality[4]	Proposed FY 2013 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[5]	Proposed FY 2013 MGCRB Reclassifications[6]	Proposed Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality[7]	Proposed Application of the Frontier Wage Index[8]	Proposed FY 2013 Out-Migration Adjustment[9]	Expiration of MDH Status[10]	Proposed Hospital Readmissions Reduction Program[11]	All Proposed FY 2013 Changes[12]
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
200 or more beds	47	1.8	0.0	-0.2	-0.1	3.0	-0.3	0.0	0.0	0.0	-0.3	1.1
Urban by Region:												
New England	120	2.3	0.0	1.0	1.0	7.0	3.1	0.0	0.0	0.0	-4.0	-4.0
Middle Atlantic	318	2.3	0.0	0.0	0.0	0.1	-0.2	0.0	0.0	0.0	-0.5	0.5
South Atlantic	377	2.3	0.0	-0.4	-0.4	-0.4	-0.4	0.0	0.0	0.0	-0.3	0.8
East North Central	396	2.3	0.0	0.1	0.2	-0.2	-0.4	0.0	0.0	0.0	-0.3	1.2
East South Central	151	2.3	0.0	-0.8	-0.7	-0.5	-0.3	0.0	0.0	0.0	-0.4	0.5
West North Central	165	2.2	0.0	0.6	0.6	-0.6	-0.4	0.7	0.0	-0.1	-0.2	1.8
West South Central	370	2.3	0.0	-0.2	-0.2	-0.6	-0.4	0.0	0.0	-0.1	-0.2	1.1
Mountain	157	2.1	0.0	-0.2	-0.2	-0.3	-0.1	0.2	0.0	0.0	-0.1	1.2
Pacific	380	2.3	-0.1	0.7	0.6	-0.2	0.9	0.0	0.0	0.0	-0.2	2.4
Puerto Rico	51	2.2	0.0	0.3	0.2	-0.8	0.2	0.0	0.0	0.0	0.0	1.7
Rural by Region:												
New England	23	1.9	-0.1	-0.1	-0.2	2.3	-0.4	0.0	0.0	-3.5	-0.1	-2.1
Middle Atlantic	69	1.6	-0.1	-0.2	-0.3	1.8	-0.3	0.0	0.0	-1.3	-0.3	-0.5
South Atlantic	164	1.9	-0.1	-0.6	-0.7	2.7	-0.3	0.0	0.1	-0.6	-0.4	-0.3
East North Central	120	1.7	0.0	-0.1	-0.1	1.5	-0.2	0.0	0.1	-1.7	-0.2	-0.9
East South Central	170	2.2	0.0	-0.4	-0.4	2.9	-0.4	0.0	0.1	-0.1	-0.4	-0.1
West North Central	98	1.2	0.0	-0.2	-0.2	1.2	-0.2	0.2	0.1	-1.2	-0.2	-0.7
West South Central	181	2.0	0.0	0.0	0.0	2.2	-0.3	0.0	0.2	-0.2	-0.5	-0.5

	No. of Hospitals[1]	Proposed Hospital Rate Update and Documentation and Coding Adjustment[2]	Proposed FY 2013 Weights and DRG Changes with Application of Recalibration Budget Neutrality[3]	Proposed FY 2013 Wage Data with Application of Wage Budget Neutrality[4]	Proposed FY 2013 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[5]	Proposed FY 2013 MGCRB Reclassifications[6]	Proposed Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality[7]	Proposed Application of the Frontier Wage Index[8]	Proposed FY 2013 Out-Migration Adjustment[9]	Expiration of MDH Status[10]	Proposed Hospital Readmissions Reduction Program[11]	All Proposed FY 2013 Changes[12]
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
Mountain	65	1.2	0.0	0.0	0.0	0.5	-0.1	0.8	0.0	0.0	-0.1	0.6
Pacific	29	1.3	-0.1	-0.1	-0.2	1.0	-0.2	0.0	0.0	-0.1	-0.1	0.0
Puerto Rico	1	2.2	0.7	0.8	1.4	-0.9	-0.4	0.0	0.0	0.0	0.0	3.7
By Payment Classification :												
Urban hospitals	2 500	23.0	0.0	0.0	0.0	2.0	0.0	1.0	0.0	0.0	3.0	1.0
Large urban areas	1,375	2.3	0.0	0.2	0.2	-0.3	0.0	0.0	0.0	0.0	-0.3	1.1
Other urban areas	1,125	2.3	0.0	-0.2	-0.1	0.0	0.1	0.1	0.0	0.0	-0.2	1.0
Rural areas	905	1.8	0.0	-0.2	-0.2	1.7	-0.3	0.0	0.1	-1.0	-0.3	-0.5
Teaching Status:												
Nonteaching	2,376	2.2	0.0	-0.1	-0.1	0.3	0.1	0.0	0.0	-0.3	-0.3	0.7
Fewer than 100 residents	789	2.3	0.0	0.1	0.1	-0.1	-0.1	0.1	0.0	0.0	-0.3	1.1
100 or more residents	240	2.3	0.0	0.1	0.1	-0.2	0.0	0.0	0.0	0.0	-0.3	0.8
Urban DSH:												
Non-DSH	758	2.3	0.0	0.2	0.2	-0.2	0.0	0.0	0.0	-0.3	-0.3	0.5
100 or more beds	1,523	2.3	0.0	0.0	0.0	-0.2	0.0	0.1	0.0	0.0	-0.3	1.1
Less than 100 beds	327	2.3	0.0	0.0	0.1	-0.1	0.2	0.1	0.0	-0.4	-0.2	1.2
Rural DSH:												
SCH	269	1.1	-0.1	0.0	-0.2	0.5	-0.1	0.0	0.0	0.0	-0.3	-0.8
RRC	210	1.9	0.0	-0.1	-0.1	2.6	-0.3	0.0	0.0	-0.5	-0.3	0.6
100 or more beds	32	2.3	-0.1	-0.4	-0.4	1.3	-0.4	0.0	0.2	-0.8	-0.5	-0.3

	No. of Hospitals[1]	Proposed Hospital Rate Update and Documentation and Coding Adjustment[2]	Proposed FY 2013 Weights and DRG Changes with Application of Recalibration Budget Neutrality[3]	Proposed FY 2013 Wage Data with Application of Wage Budget Neutrality[4]	Proposed FY 2013 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[5]	Proposed FY 2013 MGCRB Reclassifications[6]	Proposed Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality[7]	Proposed Application of the Frontier Wage Index[8]	Proposed FY 2013 Out-Migration Adjustment[9]	Expiration of MDH Status[10]	Proposed Hospital Readmissions Reduction Program[11]	All Proposed FY 2013 Changes[12]
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
Less than 100 beds	286	2.3	0.0	-0.6	-0.6	1.0	-0.3	0.1	0.4	-2.2	-0.4	-2.6
Urban teaching and DSH:												
Both teaching and DSH	815	2.3	0.0	0.0	0.1	-0.3	-0.1	0.1	0.0	0.0	-0.3	1.0
Teaching and no DSH	147	2.3	-0.1	0.5	0.4	-0.1	0.2	0.0	0.1	0.0	-0.3	0.7
No teaching and DSH	1,035	2.3	0.0	-0.1	-0.1	0.0	0.3	0.0	0.0	0.0	-0.3	1.3
No teaching and no DSH	503	2.3	0.0	0.1	0.1	-0.4	-0.1	0.1	0.0	0.0	-0.3	0.9
Special Hospital Types:												
RRC	199	2.3	0.0	0.1	0.2	3.0	-0.4	0.1	0.0	-0.8	-0.3	0.9
SCH	340	1.1	-0.1	-0.2	-0.3	0.3	0.0	0.1	0.1	0.0	-0.2	-0.4
Former MDH	195	2.3	0.0	-0.4	-0.4	0.4	-0.2	0.0	0.3	-6.1	-0.5	-7.0
SCH and RRC	101	1.2	-0.1	0.1	0.0	0.7	-0.1	0.1	0.0	0.0	-0.2	0.4
Former MDH and RRC	17	2.3	0.1	0.3	0.4	1.2	-0.4	0.0	0.0	-15.2	-0.3	-14.8
Type of Ownership:												
Voluntary	1,970	2.2	0.0	0.1	0.1	0.0	0.0	0.1	0.0	-0.1	-0.3	0.8
Proprietary	866	2.3	0.1	-0.3	-0.2	0.1	-0.1	0.0	0.0	-0.1	-0.3	1.1
Government	560	2.2	0.0	-0.2	-0.2	-0.1	-0.1	0.0	0.0	-0.1	-0.3	0.9

	No. of Hospitals[1]	Proposed Hospital Rate Update and Documen-tation and Coding Adjust-ment[2]	Proposed FY 2013 Weights and DRG Changes with Applica-tion of Recalibra-tion Budget Neutrality[3]	Proposed FY 2013 Wage Data with Applica-tion of Wage Budget Neutrality[4]	Proposed FY 2013 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibrati on Budget Neutrality[5]	Proposed FY 2013 MGCRB Reclassi-fications[6]	Proposed Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality[7]	Proposed Applicati on of the Frontier Wage Index[8]	Proposed FY 2013 Out-Migra-tion Adjust-ment[9]	Expira-tion of MDH Status[10]	Proposed Hospital Readmis-sions Reduction Program[11]	All Proposed FY 2013 Changes[12]
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
Medicare Utilization as a Percent of Inpatient Days:												
0-25	377	2.2	0.0	0.1	0.1	-0.3	0.0	0.0	0.0	0.0	-0.2	1.8
25-50	1,834	2.3	0.0	0.0	0.0	-0.2	0.0	0.1	0.0	0.0	-0.3	1.0
50-65	968	2.2	0.0	0.0	0.1	0.7	0.1	0.0	0.0	-0.4	-0.3	0.4
Over 65	168	2.1	-0.1	-0.3	-0.3	0.6	0.1	0.1	0.1	-1.2	-0.5	-0.5
Proposed FY 2013 Reclassifications by the Medicare Geographic Classification Review Board:												
All Reclassified Hospitals	755	2.2	0.0	0.2	0.2	2.2	0.3	0.0	0.0	-0.1	-0.3	0.9
Non-Reclassified Hospitals	2,650	2.3	0.0	-0.1	0.0	-0.7	-0.1	0.1	0.0	-0.1	-0.3	0.9
Urban Hospitals Reclassified	420	2.3	0.0	0.3	0.4	1.9	0.5	0.0	0.0	0.0	-0.4	1.1
Urban Non-reclassified	2,025	2.3	0.0	-0.1	0.0	-0.7	-0.1	0.1	0.0	0.0	-0.3	1.0
Hospitals, FY 2013:												
All Rural Hospitals	335	1.8	0.0	-0.2	-0.2	3.1	-0.3	0.0	0.0	-0.5	-0.3	0.2
Reclassified FY 2013:												

	No. of Hospitals[1]	Proposed Hospital Rate Update and Documentation and Coding Adjustment[2]	Proposed FY 2013 Weights and DRG Changes with Application of Recalibration Budget Neutrality[3]	Proposed FY 2013 Wage Data with Application of Wage Budget Neutrality[4]	Proposed FY 2013 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[5]	Proposed FY 2013 MGCRB Reclassifications[6]	Proposed Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality[7]	Proposed Application of the Frontier Wage Index[8]	Proposed FY 2013 Out-Migration Adjustment[9]	Expiration of MDH Status[10]	Proposed Hospital Readmissions Reduction Program[11]	All Proposed FY 2013 Changes[12]
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
Rural Non-reclassified Hospitals	524	1.7	-0.1	-0.3	-0.4	-0.2	-0.3	0.1	0.3	-1.3	-0.3	-1.8
FY 2013:												
All Section 401 Reclassified Hospitals:	46	1.8	0.0	0.5	0.5	-0.6	-0.1	0.0	0.0	-2.6	-0.2	-1.5
Other Reclassified Hospitals (Section 1886(d)(8)(B))	62	2.0	-0.1	-0.2	-0.2	2.9	-0.4	0.0	0.0	-3.1	-0.3	-2.4
Specialty Hospitals												
Cardiac Specialty Hospitals	18	2.3	0.1	-0.2	-0.1	-0.8	0.0	0.6	0.0	0.0	-0.1	2.7

1 Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2011, and hospital cost report data are from reporting periods beginning in FY 2009 and FY 2008.

2 This column displays the payment impact of the proposed hospital rate update and documentation and coding adjustment including the 2.1 percent adjustment to the national standardized amount (the 3.0 percent proposed market basket update reduced by the 0.8 percentage point for the proposed multifactor productivity adjustment and the 0.1 percentage point reduction under the Affordable Care Act) and the 0.2 percent documentation and coding adjustment to the national standardized amount (-2.7 documentation and coding adjustment and 2.9 percent return to the rate to account for the one-time documentation and coding recoupment from FY 2012). In addition, it displays the payment impact of the proposed hospital rate update of 2.1 percent and the proposed documentation and coding adjustment of -1.3 percent to the hospital-specific rate.

3 This column displays the payment impact of the proposed changes to the Version 30.0 GROUPER and the recalibration of the MS-DRG weights based on FY 2011 MedPAR data in accordance with section 1886(d)(4)(C)(iii) of the Act. This column displays the application of the proposed recalibration budget neutrality factor of 0.998546, in accordance with section 1886(d)(4)(C)(iii) of the Act.

4 This column displays the payment impact of the proposed update to wage index data using FY 2009 cost report data This column displays the neutrality factor, and is calculated in accordance with section 1886(d)(3)(E)(i) of the Act. The proposed wage budget neutrality factor is 1.000563.

5. This column displays the combined payment impact of the proposed changes in Columns 3 through 4 and the proposed cumulative budget neutrality factor for MS-DRG and wage changes in accordance with section 1886(d)(4)(C)(iii) of the Act and section 1886(d)(3)(E) of the Act. The proposed cumulative wage and recalibration budget neutrality factor of 0.999108 is the product of the wage budget neutrality factor and the recalibration budget neutrality factor.

6 Shown here are the proposed effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB). The effects demonstrate the FY 2013 payment impact of going from no reclassifications to the proposed reclassifications scheduled to be in effect for FY 2013. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the proposed geographic budget neutrality factor of 0.991436.

7. This column displays the proposed effects of the rural floor and imputed floor, including the Affordable Care Act requirement that the floor budget neutrality is at a 100 percent national level adjustment. This column does not reflect the alternative temporary methodology proposed beginning in FY 2013; we note that the impact of that proposal is discussed separately and would have a negligible impact on budget neutrality. The proposed rural floor and imputed floor budget neutrality factor is 0.992243.

8 This column shows the proposed impact of the policy required under section 10324 of the Affordable Care Act that hospitals located in frontier States have a wage index no less than 1.0.

9./ This column displays the proposed impact of section 505 of Pub. L. 108-173, which provides for an increase in a hospital's wage index if the hospital qualifies by meeting a threshold percentage of residents of the county where the hospital is located who commute to work at hospitals in counties with higher wage indexes.

10. This column displays the impact of the expiration of MDH status, under section 3124 of the Affordable Care Act, a non-budget neutral payment provision.

11. This column displays the impact of the proposed implementation of the Hospital Readmissions Reduction Program, section 3025 of the Affordable Care Act, a non-budget neutral provision that adjusts a hospital’s payment for excess readmissions.

12. This column shows the proposed changes in payments from FY 2012 to FY 2013. It reflects the impact of the proposed FY 2013 hospital update, the proposed adjustments due to the documentation and coding. It also reflects proposed changes in hospitals' reclassification status in FY 2013 compared to FY 2012. It incorporates all of the changes displayed in Columns 2, 5, 6, 7, 8, 9, 10 and 11 (the changes displayed in Columns 3 and 4 are included in Column 5). The sum of these impacts may be different from the percentage changes shown here due to rounding and interactive effects.